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Introduction

The medical treatment guidelines/review criteria contained herein were developed by the Washington State Medical Association Industrial Insurance Advisory Committee in collaboration with the Office of the Medical Director. These guidelines/review criteria are published by the Department of Labor and Industries as educational tools for providers.

In addition, the guidelines/review criteria are implemented in prospective utilization management programs, the responsibility for which is solely that of the Department of Labor and Industries.

Note: *For more copies of the Medical Treatment Guidelines please write to: L&I Warehouse, Department of Labor and Industries, P.O. Box 44843, Olympia, Washington 98504-4843.*

Review, Regulate, or Reform?

WHAT WORKS TO CONTROL WORKERS' COMPENSATION MEDICAL COSTS

Thomas W. Grannemann, Editor

WORKERS COMPENSATION RESEARCH INSTITUTE
Published in 1994

Gary Franklin and
Roy Plaeger-Brockway[1]

Medical Practice Guidelines in Washington Workers' Compensation

Background

The Washington State Medical Association (WSMA) Industrial Insurance Advisory Committee, in conjunction with the Washington State Department of Labor and Industries (L&I), has developed a process for establishing medical practice guidelines. Under authority of WAC 296-20-01001, the WSMA committee advises and assists L&I on issues broadly related to the quality of medical care received by injured workers. Since September 1988, two working subcommittees of the WSMA committee have met on a monthly basis to address 1) medical practice guidelines and 2) issues related to work disability among injured workers. These two subcommittees were established simultaneously because, in the view of WSMA members, injured workers receiving surgery were less likely to recover if disability-related issues were prominent at the time of surgery. Because of the complexity of the disability issue, the work of these two subcommittees has been difficult to merge. Nonetheless, the most recent guidelines (e.g. lumbar fusion) have incorporated disability related issues.

The need to establish practice guidelines was recognized by the members of the Washington State Medical Association committee in 1988, when the inpatient utilization review (UR) program was established. This program provides preadmission medical necessity review for inpatient admissions, particularly related to surgical procedures. Earlier in 1988 L&I had established and published admission criteria for the inpatient medical treatment of back pain (for those that did not require surgery). Within one year of publishing these criteria, medical back admissions for the department fell by 60 percent. Surprisingly, a statewide sentinel effect was also seen in hospital discharge data. The inpatient UR program was originally contracted to an out-of-state vendor who used proprietary surgical criteria to establish medical necessity. Although these criteria are used nationally by insurance companies, they were felt to be inadequate in detail and specificity for L&I's purpose of assuring quality.

The first WSMA medical guidelines subcommittee meeting occurred in September 1988, in response to a L&I request to assist with development of guidelines for lumbar fusion. After three to four months of meetings, the subcommittee, which included several prominent spine surgeons from the Seattle area, presented a draft of guidelines for fusion to the full WSMA committee. In 1989, L&I published the fusion guidelines.

Since the publication of the medical back and fusion guidelines, 11 other guidelines have been established and published (Table 1). Although most have been guidelines for surgery, one recently developed guideline is for use of scheduled drugs for non-

[1]This work was done in full collaboration with the Washington State Medical Association Industrial Insurance Advisory Committee.

malignant pain. Another guideline, related to causality and treatment of carpal tunnel syndrome, has just been published.

The WSMA/L&I Medical Practice Guideline Process

The process used by the WSMA medical guidelines subcommittee is a combination of scientific evidence and community-based expert opinion. Although the consensus process is relatively informal, most aspects of the process for each guideline have been quite consistent, employing the following steps.

- Prioritization of guidelines
- Consensus development
- Formatting a decision-making algorithm
- Implementation
- Evaluation

Table 1. WSMA Practice Guidelines for Washington Workers' Compensation

Guideline	Date Published
Medical back admissions	1988
Lumbar arthrodesis	1989
Lumbar laminectomy	1990
Thoracic outlet release	1990
Cervical laminectomy	1991
Knee surgery	1991
Shoulder surgery	1991
Ankle/foot surgery	1992
Scheduled drug use	1992*
Lumbar arthrodesis	1994
Lumbar MRI	1994
Shoulder MRI	1994
Carpal tunnel surgery	1994

* WSMA Bulletin

PRIORITIZATION OF GUIDELINES

For the most part, prioritization has depended on 1) frequency of the problem, 2) cost, 3) poor outcomes or, 4) weak biologic plausibility. The lumbar fusion guideline, for example, was addressed first since no proprietary criteria for fusion were available. Other surgical guidelines were addressed because they are frequently performed (e.g., back, neck and knee). Both lumbar fusion and thoracic outlet surgery are relatively infrequent, but neither has strong clinical trial support nor clear biologic plausibility.

CONSENSUS DEVELOPMENT

Consensus development has generally taken place between the permanent members of the subcommittee (orthopedic surgeon, physiatrist, occupational medicine physician, neurologist, neurosurgeon) and *ad hoc* invited physicians who are clinical experts in the topic to be addressed. One hallmark of these discussions is that since few of the guidelines being discussed have a scientific basis, disagreement on specific points is common. Following the initial meeting on each guideline, subsequent meetings are only attended by permanent members unless information gathering from invited physicians is complete.

In order to reach consensus, the following assumptions are made.

1. The (surgical) guideline is meant to increase the proportion of surgical requests authorized for workers who truly require surgery, and to decrease the proportion of such authorizations among workers who do not fall within the consensus guideline.

2. The guideline is meant to be a gold standard for the majority of requests, but for the minority of workers who appear to fall outside of the guideline and whose complexity of clinical findings exceeds the specificity of the guideline, a further review by a specialty-matched physician is conducted.

3. The guideline is further refined after input from other community-based practicing physicians.

4. The guideline is evaluated to determine if it is having a beneficial effect.

5. The guideline-setting process will be iterative, that is, although initial guidelines may be quite liberally constructed, subsequent tightening of the guideline would occur as other national guidelines are set, or other scientific evidence (e.g., from outcomes research) becomes available.

Assumption number two is particularly important and warrants elaboration. The intention of the WSMA Medical Guidelines Subcommittee was to develop treatment guidelines that would be implemented in a nonadversarial way. The subcommittee tried to distinguish between clear-cut indications for procedures and indications that were questionable. The expectation was that when surgery was requested for a patient with

clear-cut indications, the request would be approved by nurse consultants. However, if such clear-cut indications were not present, the request would not be automatically denied. Instead, it would be referred to a physician consultant who would review the patient's file, discuss the case with the requesting surgeon, and make recommendations to the claims manager. The flexibility built into this decision making process was important in two ways. First, it enabled the subcommittee to develop surgical indications fairly quickly, since the members were aware that the indications would not be applied in a heavy-handed way. Second, it played a major role in legitimizing the work of the subcommittee in the eyes of practicing physicians in Washington.

FORMATTING A DECISION MAKING ALGORITHM

Once the principles of the guideline are reached by consensus, these principles are placed in a format consisting of and/or statements intended to aid professional nurse reviewers in deciding whether a particular surgical request falls within the guideline. (See lumbar laminectomy example, Appendix A).

IMPLEMENTATION

Most guideline development efforts, particularly at the federal level, stress dissemination of guidelines and hoped for change in physician behavior. The Institute of Medicine's report on development of practice guidelines (1992) differentiated between guidelines (intended for practitioners) and medical review criteria (intended to assess care).

It has become clear that, without a method of implementation, medical practice guidelines may be inconsistently and informally applied. Most of the surgical guidelines established by WSMA have been implemented in the context of the inpatient UR program. It has been critical in contract negotiations with UR vendors to specify that the vendor is willing to substitute WSMA-generated guidelines for less specific standards already in use by the company. More recently, the Department of Labor and Industries initiated an outpatient UR program, and this has allowed full implementation of guidelines related to outpatient procedures (e.g., carpal tunnel surgery, MRIs).

EVALUATION

The Department is developing a database sufficient to provide continuous evaluation of all newly implemented guidelines. Current evaluation efforts, dependent on retrospective vendor reports, are labor intensive and are not responsive enough to emerging needs. The new database could identify both provider indicators of outlying behavior, as well as worker-based health outcomes (e.g., time loss duration post surgery).

The Relationship of the WSMA/L&I Medical Practice Guideline Process to National and Statewide Guideline Efforts

Three specific types of guidelines may be differentiated. The first, a *point of service guideline*, is one which is used to determine if a specific medical intervention is warranted at a given point in time. Most of L&I's surgical guidelines would fall in this category. A second variety of guidelines is one which would be used to follow a patient over time, the guideline perhaps containing a number of red flags to indicate the risk for an adverse outcome. Such a guideline could be called a *longitudinal guideline*, one which helps in prospectively following patients. The forthcoming guideline for treating low back pain from the Agency for Health Care Policy and Research is an example. L&I's new guideline for use of scheduled drugs for nonmalignant pain would also fall in this category. A third type of guideline would relate to criteria for use of new technologies. Similar *technology evaluation guidelines* have been developed by the National Blue Cross/Blue Shield Association (Table 2), and would be more likely related to system-wide approaches to payment for new technologies whose efficacy is not clearly demonstrated. Technologies with proven efficacy would be dealt with as a point of service guideline.

Table 2. Blue Cross/Blue Shield National Association Technology Evaluation Criteria*

1.	The Scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
2.	The technology must improve net health outcome.
3.	The technology must be as beneficial as any established alternatives.
4.	The improvement must be attainable outside the investigational setting.
5.	The technology must have final approval from the appropriate government regulatory bodies.

* Technologies must meet all five criteria to be recommended for coverage.

Woolf (1992) outlines four common approaches for developing practice guidelines that range from relatively unstructured, informal methods to very formal, structured approaches. Woolf characterizes the approaches as:

1. Informal consensus development, the most common approach, consists of a simple literature review and an unstructured consensus process.

2. Formal consensus development uses a structured approach to assess expert opinion and to reach agreement on recommendations.

3. Evidence-base guideline development bases recommendations directly on scientific evidence, and research findings are stressed over expert opinion.

4. Explicit guideline development is based on analyzing the potential benefits, harms, and costs of available interventions, estimating the possibility of the

outcomes, and comparing the desirability of the outcomes based on patient preferences.

NATIONAL DEVELOPMENTS

The New England Medical Centers Institute for the Improvement of Medical Care and Health recently conducted a survey of eight prominent organizations that have innovative guideline development programs, (Audet, 1990). The organizations surveyed all have systematic approaches to guideline development and illustrate the spectrum of approaches described by Woolf. The various approaches provide a good point of reference for evaluating L&I's guideline development efforts.

Goals of guideline development. The goals of guideline development are fairly common across the organizations surveyed. All eight programs indicate that the goal of their program is to improve the quality and effectiveness of care. Six of the eight organizations surveyed stated that cost control is a secondary reason for developing guidelines.

Methods for developing practice guidelines. Guideline development methods vary considerably in terms of the approaches to reviewing current evidence, the use of national versus local experts, and consensus development methods.

Review of Current Evidence. The Harvard Community Health Plan, a leading HMO, relies on comparatively informal methods. The leader of a guideline effort conducts an informal literature review and distributes key papers to a consensus group. This method is similar to the approach used by L&I and is characterized by Woolf as *informal consensus*. In contrast, RAND and Value Health Sciences conduct an exhaustive review of the literature. The American College of Physicians uses an even more formal review process where experts are selected to summarize the literature in scholarly background papers. The papers include a description of methods used to analyze the background data from the literature.

Experts and Consensus Development. The Harvard Community Health Plan employs a nominal group process followed by a Delphi procedure which draws on local physicians who are likely users of the guidelines.

This is comparable to the approach used by L&I, although L&I involves fewer end-users. RAND and Value Health Sciences convene a group of nationally known experts who apply a rating system to the findings from extensive literature reviews, followed by a Delphi procedure. The American College of Physicians develops position papers which undergo review by all appropriate specialty societies.

Guideline Implementation. All eight organizations surveyed acknowledged they pay more attention to guideline development than they do to guideline implementation. Harvard Community Health Plan, Value Health Sciences, and MetroHealth employ computer software combined with monitoring and training programs to promote use of

guidelines. In comparison, the American College of Physicians and the American Medical Association have no implementation strategy other than the dissemination of the guideline. L&I's application of guidelines varies; although most guidelines are rigorously applied through utilization review programs, the scheduled drug use guideline has been widely disseminated by WSMA and used internally, but has not been formally implemented in a UR program.

Evaluation Research. Most organizations surveyed conceded that they devote the bulk of their resources to guideline development and commit few resources to evaluating guideline impacts. However, Harvard Community Health Plan is conducting a controlled study to evaluate the impacts of some of its guidelines. MetroHealth is also conducting a similar study. Value Health Sciences conducts hospital chart audits to determine the effectiveness of their preadmission review programs. However, evaluation efforts are considered relatively undeveloped by the survey authors. L&I's emphasis on evaluation puts the agency in a leading position relative to other model programs.

Summary. There is an apparent consensus on the goals of guideline development among the organizations surveyed, namely, to improve the quality of care and control costs. However, there is a spectrum of approaches to guideline development which vary from the relatively informal methods used by the Harvard Community Health Plan to the highly structured methods used by RAND, Value Health Sciences and the American College of Physicians. L&I's method tends to fall on the informal end of the spectrum and is most like the approach used by the Harvard Community Health Plan. However, this program is somewhat more developed than L&I's and may be a useful reference point for program enhancements. HCHP has been cited as a model program by Group Health Cooperative of Puget Sound.

Details of the Harvard Community Health Plan. The Harvard Community Health Plan (HCHP) is a 400,000 member HMO in Massachusetts. In 1986 it began what is now considered to be a prototype approach to developing practice standards. (Gottlieb, 1990) The program focuses on developing clinical algorithms for health problems that are commonly encountered by the HMO's practicing physicians. The algorithms outline a step-wise process for diagnosing and treating common health problems. The basis of the guideline formation process is to combine pertinent evidence from the medical literature, expert consultants, and HCHP practitioners to generate consensus algorithms.

HCHP initially developed a CME workshop to introduce practitioners to the program and encourage their involvement in algorithm development. Early concerns about *cookbook medicine* and worries about a top-down approach to developing and applying standards were addressed through open communication in the workshops. This apparently led to building support for the program among practicing physicians. A hallmark of both the HCHP and L&I programs is reliance on practicing clinicians to develop guidelines.

The program has completed and distributed 31 guidelines and has 50 ore underway. More than 300 physicians have been involved in the process. As the program has evolved, criteria have been developed for selecting topics for guideline development (Table 3). In addition, the program has outlined a thoughtful process for developing guidelines (Table 4). The program is also experimenting with innovative education and training methods for implementing guidelines.

LOCAL DEVELOPMENTS IN WASHINGTON STATE

Group Health Cooperative of Puget Sound is currently developing a clinical guidelines program. They are looking at the HCHP guidelines program for direction. The First Choice Health Network is using automated guidelines known as *Patterns of Treatment* which were developed by Don Herrington, MD, of California. Another insurer in the state is also using this software. First Choice Network indicates that their initial attempts at sharing the comparative statistics produced by the software has been well received by their physicians. Furthermore, physicians appear to be using the profiles to evaluate their practice patterns in relation to their peers.

Table 3. Criteria for Choosing Clinical Algorithm Topics

- Common clinical conditions
- Unexplained variation in clinical practice (perceived or documented)
- Unexplained variation in utilization of limited or costly resources
- General clinical uncertainty or controversy
- Uncertain indications for risky or costly intervention
- Internal resource access or supply constraints
- Apparent risk management problem
- Introduction of new diagnostic test, therapeutic procedure or medication
- Quality of care problem perceived by patients, clinicians or managers

SOURCE: Audet, 1990

The 1990 Study of State Purchased Health Care recommended that the state establish a medical directorship that will work with local practitioners to establish practice standards. The study also recommended that state agencies develop methods to evaluate provider compliance with the standards and to provide feedback to practitioners. These recommendations were superseded by the Washington Health Services Act of 1993, which authorized the new Health Services Commission and the Department of Health to promulgate rules in relationship to practice *indicators*, and that such *indicators* be based on the best available scientific evidence and consensus expert opinion.

Table 4. The Algorithm Development Process at HCHP

Project Planning

1. Identification of topic
2. Identification of intended users
3. Determination of suitability for *local* or *central* consensus
4. Identification and selection of group leader
5. Identification and selection of members of consensus group

Consensus Algorithm Development

6. Literature search and summary
7. *Seed algorithm* construction
8. Review of literature and seed algorithm by consensus group members
9. Brief algorithm and consensus development training
10. Consensus development via nominal group process and/or Delphi method

Algorithm Review

11. Identification of *essential nodes* for possible measurement
12. Identification and selection of *algorithm keeper*
13. Selection of date for next review and revision
14. Review and approval of algorithm

Implementation

15. Distribution of algorithm with request for feedback
16. Design of implementation strategies

SOURCE: Audet, 1990

Impact of the WSMA/L&I Medical Practice Guidelines

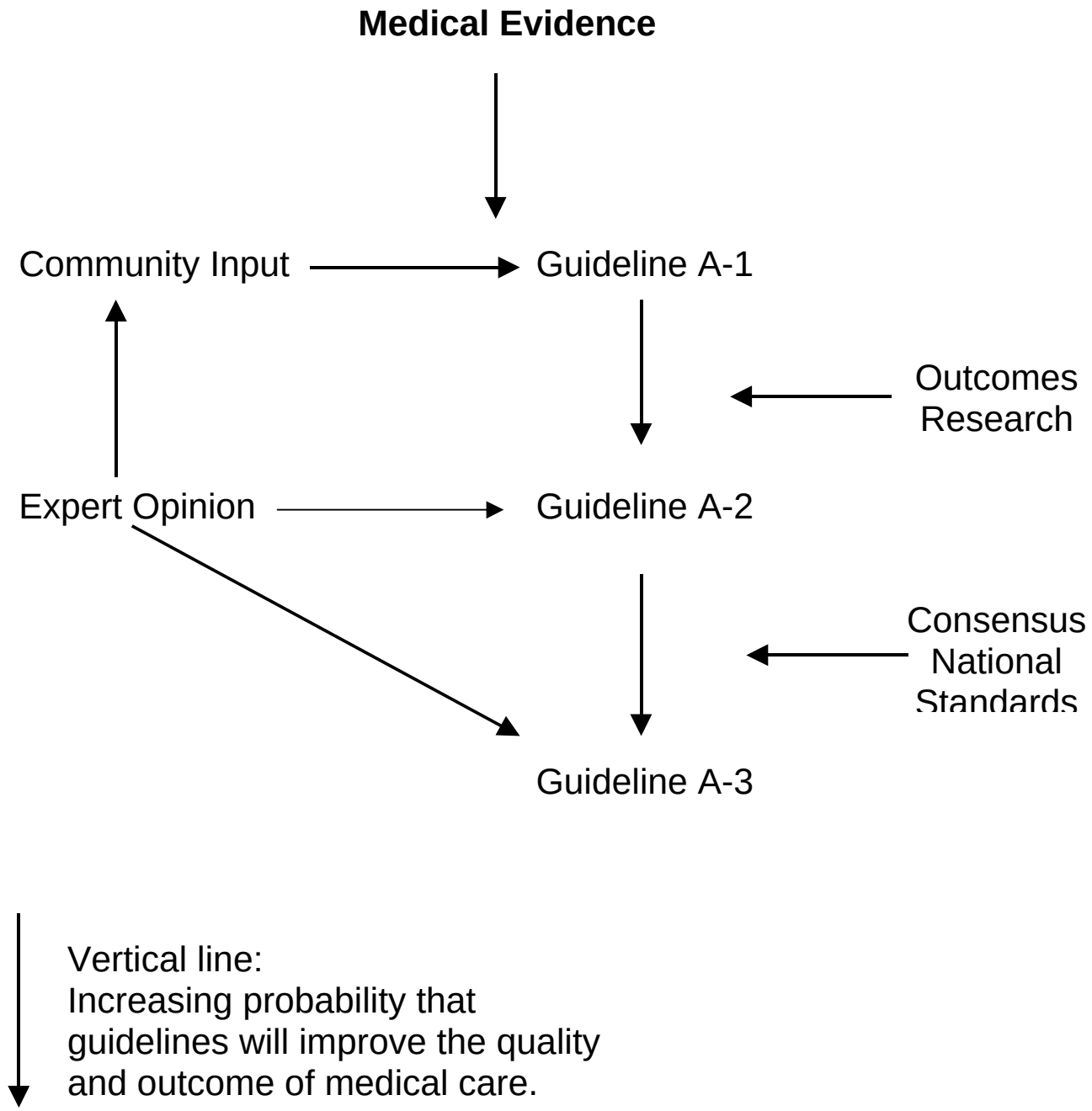
Plans are currently in place to evaluate the impact of the guidelines, and the Department has done a preliminary analysis of the impact of the original lumbar fusion guidelines. A 10-month experience in 1989 was reviewed. During this time, approximately 17 percent of requests for lumbar fusion were denied. Moreover, the workers in this group experienced claim resolution in the subsequent two years significantly more frequently (36%) than those who had fusion surgery (22%, $p < 0.05$). A more recent preliminary analysis of the fusion experience in 1991 revealed that the guideline had an initial significant effect but that this effect has only marginally increased with time. The implication was that a more specific standard would be in order at this time, and that any sentinel effect of inter-physician education had already been maximized.

Relationship to Outcomes Research

The guideline setting process should be iterative in nature, with increasingly specific guidelines produced as more scientific evidence becomes available (Figure 1). The Occupational Epidemiology and Health Outcomes program at the University of Washington, funded by Accident and Medical Aid fund monies, conducts outcomes research related to the L&I guidelines process. Outcome studies related to carpal tunnel surgery (Adams, 1994), lumbar fusion (Franklin, Haug, 1994), and thoracic outlet (Adams, 1994), lumbar fusion (Franklin, Haug, 1994), and thoracic outlet surgery (Franklin, Fulton-Kehoe, 1994), have been completed and have led to substantial changes in previously published guidelines. The principal example is the newly published guideline on lumbar fusion (Page 32), the most specific such guideline currently available. A new guideline on thoracic outlet surgery, not yet published, will require objective neurologic loss prior to approval of such surgery.

This iterative process stands in contrast to the method in some states of placing guidelines in regulation. Although such regulation could aid in the dissemination and quality oversight of guidelines, flexibility in creating updated guidelines might be limited.

Figure 1
WSMA/DLI Iterative Process for Setting Medical Guidelines



Legal Implications of the Guideline Process

Two principal legal questions have been addressed in regard to guideline development:

1. Are the physicians participating in the WSMA/L&I guideline development process protected from tort action?

2. Are practicing physicians who adhere to such guidelines protected from tort action?

In regard to question 1, an assistant attorney general's informal opinion in 1989 was that any physician participating on a voluntary (non-pay) basis in a medical committee established in RCW/WAC for quality assurance purposes would be defended by the full legal resources of the state. The principal successful action taken in the past against physicians participating in quality assurance decisions utilized federal antitrust law (Patrick decision, Oregon, 1986); however subsequent federal and state legislation protects physicians against similar use of federal antitrust law. (Curran, 1989)

Little precedent exists in regard to question 2. The state of Maine has passed a statute protecting physicians who utilize guidelines established by their peers. (Main statutes, 1989-91) This statute provides an affirmative defense for physicians in malpractice situations, who were complying with their specialty's guidelines. It is likely that similar statutory protection will occur as part of health care reform efforts in other states.

An additional legal issue relates to the weight of WSMA opinion at the Board of Industrial Insurance Appeals. If an individual request for surgery does not meet WSMA's guidelines, and is rejected by L&I, it is theoretically possible that such denial of surgery could be overturned at the Board. This fundamental tension between the authority of L&I to implement WSMA community-based treatment guidelines, and the individual workers' or provider's right to appeal such decisions to the Board, will need to be resolved if guideline use in the context of worker's compensation is to be a successful effort. A related underlying assumption of the WSMA guideline process has been that specific indications for surgery ought to be biologic and not based in the adversarial relationships classically engendered in worker's compensation.

Technology Assessment

The assessment of the efficacy of emerging technologies has proved particularly vexing for L&I and other state agencies. The principal problem lies in a dual standard for approval of drugs and new devices at the FDA. Drugs must be proven to be both safe and effective when they are approved for use. New devices, on the other hand, may receive "premarket approval" based on much less stringent safety and efficacy data. Although the intent of this dual standard was to foster development of new technologies, the real effect is that relatively untested devices may gain credibility within the medical community. The Safe Medical Devices Act of 1990 (PL101-629) (DHHS FDA, 1991) gives the FDA more authority to monitor the use of premarket approved devices. For

example, hospitals may now be audited for adverse events related to devise use. Nonetheless, the responsibility for reimbursement for what are essentially investigational devices is left to third party payers. Criteria similar to those used by the Blue Cross/Blue Shield National Association (Table 2) or criteria based on improvement in net health outcome could help reconcile the worker's compensation "palliative vs. curative care" issues.

The relationship of the WSMA guideline work to Board of Industrial Insurance Appeals activity is particularly critical in the technology area. One example is use of the epidural (spinal) stimulator to treat chronic low back and leg pain. On three separate occasions between November 1990 and June 1991, the WSMA Industrial Insurance Committee reviewed safety and efficacy data on this device and voted unanimously to urge L&I not to authorize its use in any case. At least 3 cases appealing the nonauthorization have appeared before the Board, all of which have been upheld in the Department's favor. However, two of the cases were reversed at Superior Court. Although these higher court decisions are not precedent setting, L&I is working to create new regulations that would strengthen the amount of scientific evidence that would be required to justify coverage of emerging procedures and diagnostic tests. Such regulations could further clarify the authority of the WSMA guidelines committee.

A final example of the new technology dilemma facing L&I is the use of pedicle screw fixation devices by orthopedic surgeons to assist in achieving solid lumbar fusion. Most of the fixation devices in use today are not approved for use by the FDA, and research at the University of Washington has suggested adverse outcomes from their use. (Franklin, Haug, 1994) Nonetheless, nearly one-half of all fusion patients have received this device as an adjunct to lumbar fusion surgery. The new fusion guideline (Page 32) contains specific language that must be incorporated into informed consent that explicitly states the experimental nature of these devices.

Future Research and Recommendations

The hallmarks of the WSMA/L&I process for setting medical guidelines are that it is 1) driven by community-based expert opinion, 2) designed to be responsive to end users (physicians, L&I), 3) primarily based (implemented) in prospective review programs and 4) flexible enough to be iterative in nature. The iterative nature of the process is crucial in allowing for continuous improvement of guidelines based on emerging scientific evidence and national consensus efforts (Figure 1). Building on these strengths, the following recommendations should be considered:

- The WSMA/L&I guideline process has been endorsed by a formal labor-management consensus process, the statutory Workers Compensation Advisory Committee. Similar endorsement in other states could improve understanding of the value of practice guidelines in workers compensation.

- Enhancements to the current process should include:

  - Development of methodologies to maximize community-based physician input and support
  - Expansion of the capacity of L&I prospective review programs to implement longitudinal guidelines.
  - Better coordination of case management of injured workers whose care does not fall within established medical guidelines.
  - Formalization of criteria for prioritizing guidelines to meet both short and long term needs.
  - Better design of internal evaluation procedures to determine if guidelines are improving net health outcomes.

- In order to maximize limited resources, increased networking, demonstration projects and sharing of expertise should be pursued with other state and federal agencies and professional societies which are involved in the guideline development and technology assessment processes.

- The relationship of the WSMA/L&I guideline process to existing or emerging guidelines should be clarified in policy. To the extent possible in the future, guidelines in use by utilization management vendors should be available for review by the WSMA medical guidelines committee. In most cases, a WSMA/L&I guideline should be used rather than more generic or nonspecific guidelines already in use by the vendor. If a guideline is established by a nationally recognized group (e.g., RAND Corporation, Agency for Health Care Policy and Research) that a) exceeds the specificity of a WSMA/L&I guideline, b) is more clearly based on stronger scientific evidence, c) has broader consensus, and d) is implementable, then such a guideline could replace an existing WSMA/L&I guideline. However, even in this case, acceptance by the WSMA medical guidelines committee would be critical.

- For new technologies which have received premarket approval by the FDA, but whose efficacy data is unclear, the following requirements for requesting physicians are recommended:

  - The physician should have Institutional Review Board approval from their own institution (e.g., hospital, HMO) to perform the procedure
  - The physician should be part of a formal data collection effort
  - The physician should supply data to L&I and the WSMA medical guidelines committee sufficient to meet the Blue Cross/Blue Shield criteria for technology assessment.

  For those technologies which **do not** have FDA approval, but which are in use in the community, the above criteria should apply and L&I should require that appropriate informed consent language be included in guidelines (see Page 32, Lumbar Fusion Guidelines).

- The WSMA medical guidelines committee should strive to include principles of disability prevention and management in their guideline process.

- The interface between the WSMA/L&I guideline process and the role of the Board of Industrial Insurance Appeals should be clarified, perhaps in statute. At a minimum, medical expertise resident on the board could help clarify disputes in regard to use of community-based medical guidelines. The key issue here is not whether or not the WSMA Industrial Insurance Advisory Committee has the authority to establish medical guidelines for L&I, but rather whether the facts of the workers case were properly interpreted **within** the context of the guideline.

- Clear definition of key terms should be made in WAC and policy. For WAC these could include clearer definition of *experimental,* new - *technology,* and *net health* benefit. In policy, this could include *guidelines, standards,* and other key terms.

- L&I should, along with other state agencies, develop a strategic plan to a) enhance legal protection for peer reviewers and b) allow compliance with state mandated guidelines to be an affirmative defense in malpractice situations.

- The capacity of the University of Washington and L&I to conduct outcomes research on worker's compensation specific health issues should be enhanced.

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GUIDELINE FOR HOSPITALIZATION FOR LOW BACK PAIN

The following guideline replaces Criteria for Non-Surgical Hospital Admission for Acute and Chronic Low Back Pain published in Provider Bulletin 88-09.

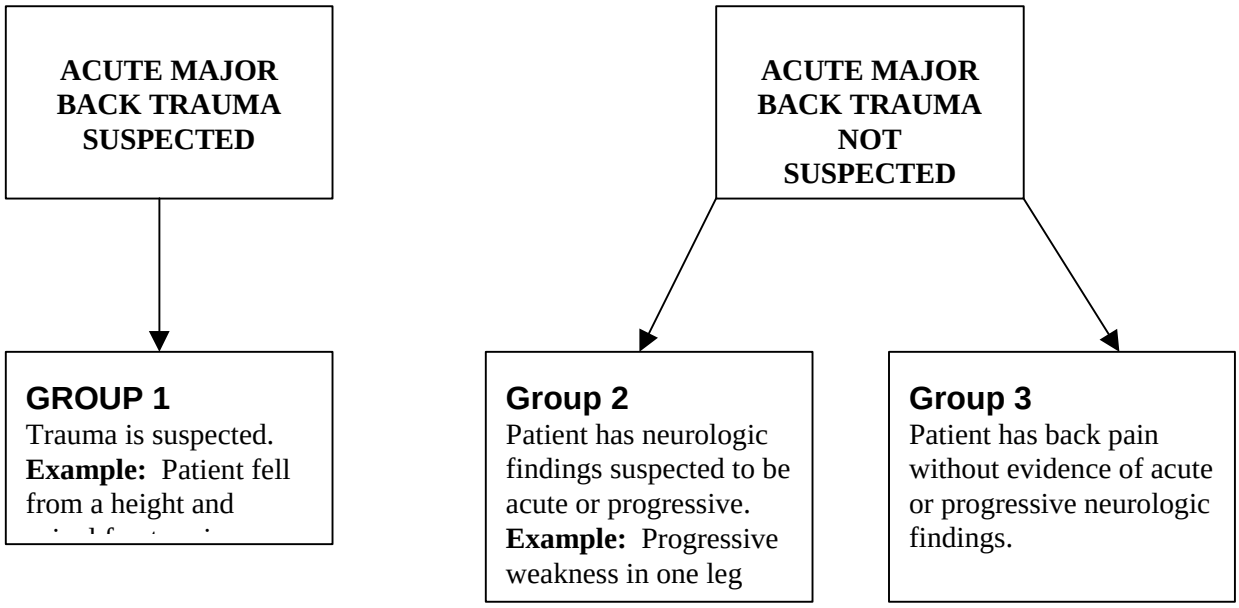
Changes in Practice Patterns:

Several years ago it was fairly common for physicians to hospitalize patients for medical management of low back pain. Typically, hospitalized patients were treated with bed rest, traction, and medication.

The frequency with which low back pain patients are hospitalized for medical management has dropped dramatically during the past ten years. This trend applies to both the injured worker population and other patient groups. For example, in 1986 there were approximately 1500 hospitalizations for medical management of low back pain among L&I patients; in 1996, the corresponding number was about 70.

The present guidelines reflect the current consensus that hospitalization is rarely needed for patients with low back pain.

CLASSIFICATION OF PATIENTS WITH LOW BACK PAIN



Guidelines for the management of these various groups or categories of medical problems are described on the following pages.

Reference: Provider Bulletin 98-05; Date Introduced: Jun. 98'

CLINICAL FEATURES	PREADMISSION EVALUATION AND TREATMENT	HOSPITAL ADMISSION CRITERIA	POST-ADMISSION MANAGEMENT
GROUP 1: Acute Major Trauma Suspected A) Back injury occurred within the past 7 days AND B) A major trauma was sustained (e.g. fall from a height, or back crushed by heavy object). **AND** C) Examining physician documents or suspects acute spinal fracture, spinal cord injury or nerve root injury.	Individualized	Individualized	Individualized
	A) Outpatient setting: Evaluation and treatment is individualized. B) Emergency Department Setting: 1) Advanced diagnostic imaging may be indicated when a patient in Group 2 comes to the Emergency Department. 2) An attempt to reach the patient's attending physician should always be made before an emergency department MD decides to order advanced imaging studies. (The attending physician is in the best position to evaluate the patient's clinical presentation and judge the usefulness of imaging studies). 3) If an imaging study is done and does NOT demonstrate an acute, lesion, for which surgery is indicated, the patient should be managed like a patient in Group 3. The patient should be discharged unless he/she is unable to perform ADLs at home.	A) If a patient has a new or progressive neurologic deficit, he/she may be hospitalized in order to facilitate surgical decision-making, to provide close observation of further progression or to help the patient compensate for neurological deficits (e.g. to determine whether the patient needs to learn intermittent catheterization). B) If a patient does NOT have a new or progressive neurologic deficit, he/she should be treated like a patient in Group 3. The only valid reason for hospitalization is that he/she cannot manage basic ADLs at home. C) If a patient is admitted through an emergency department, the decision to admit should be made with the concurrence of the attending physician, unless the attending physician cannot be reached.	A) *Duration of hospitalization should be brief*. The great majority of Group 2 patients who are admitted to a hospital can be discharged in 1-3 days (if spine surgery is not performed). B) Treatment Plan Goals 1) General Strategy – It is crucial to assess the patients' ability to perform ADLs and to identify environmental barriers to return home. a) An assessment of these factors should begin immediately upon admission. A list of barriers to discharge should be noted in the patient record. b) The ability of the patient to perform ADLs should be measured serially, e.g., can the patient ambulate to the bathroom? c) Discharge planning should begin immediately, for example: the patient's significant other should be contacted and problem solving should be undertaken regarding practical problems such as the ability to get food and ambulate to the bathroom in the home. 2) Pain Management – Review potential to benefit

CLINICAL FEATURES	PREADMISSION EVALUATION AND TREATMENT	HOSPITAL ADMISSION CRITERIA	POST-ADMISSION MANAGEMENT
			from nonsteroidals, antidepressants, opiates. **NOTE:** The Department of Labor and Industries does not cover epidural or intrathecal administration of opiates except in the peri-operative period. 3) Management of Neurological Deficits – a patient may need help with bladder catheterization or may need a brace for his/her leg. C) Diagnostic Imaging, Physician Consultants and Surgical Planning – Individualized. D) **NOTE:** Prolonged bed rest usually does more harm than good in a patient with low back pain. Admission for the purpose of bed rest is not acceptable.
Group 3: Acute Major Back Trauma Not Suspected; Patient Has Back Pain Without Evidence of Acute or Progressive Neurologic Findings A) No history of recent major trauma. **AND** B) Patient complains of back pain with or without symptoms in the legs. Occasionally patients will complain mainly of symptoms in the legs but **the evaluating physician concludes that symptoms are not caused by lumbar radiculopathy** **AND** C) No evidence of acute or progressive neurologic deficit.	A) When the attending physician initiates hospitalization from an outpatient setting: 1) The attending physician must document that he/she has given the patient an adequate trial of oral medication to control pain and that the patient has made a genuine attempt to manage ADLs at home. B) When hospitalization is initiated from an emergency room: **NOTE:** most admissions for back pain start with an injured worker going to the emergency department. 1) Advanced imaging is RARELY indicated. Advanced imaging should be ordered ONLY with the concurrence or the patient's attending physician.	A) The only valid reason for hospitalizing a patient is that he/she cannot manage basic ADLs at home. Example, the patient lives alone and is unable to get to the bathroom. B) If a patient is admitted through the emergency department, the decision to admit should be made with the concurrence of the attending physician, unless the attending physician cannot be reached.	A) *Duration of hospitalization should be brief*. The great majority of Group 3 patients who are admitted to a hospital can be discharged in less than 24 hours. B) *Treatment Plan Goals* 1) General Strategy – It is crucial to assess the patient's ability to perform ADLs and to identify environmental barriers to return to the home. a) An assessment of these factors should begin immediately upon admission. A list of barriers to discharge should be noted in the patient record b) The ability of the patient to perform ADLs should be measured serially – e.g., can the patient ambulate to the bathroom? c) Discharge planning should begin immediately, for example: the patient's significant other should be contacted and problem solving should be undertaken regarding

CLINICAL FEATURES	**PREADMISSION EVALUATION AND TREATMENT**	**HOSPITAL ADMISSION CRITERIA**	**POST-ADMISSION MANAGEMENT**
			practical problems such as the ability to get food and ambulate to the bathroom in the home. 2) Pain Management – Review potential to benefit from nonsteroidals, antidepressants, opiates. **NOTE:** The Department of Labor and Industries does not cover epidural or intrathecal administration of opiates except in the peri-operative period). Physical Activity – The patient should receive aggressive physical therapy at least twice per day. 3) Diagnostic Imaging and Physician Consultants a) These rarely need to be done while a patient is in the hospital. b) The patient's hospital stay should not be prolonged simply to facilitate imaging or consultation while he/she is still in the hospital. The patient should be discharged as soon as he/she is able to manage basic ADLs. Imaging and consultation can be done as an outpatient. C) **NOTE:** Admission for the purpose of bed rest or traction alone is not acceptable. D) A patient should not be admitted to a hospital that does not have the capacity to assess ADLs, develop a treatment plan, & provide physical therapy within the first 24 hours.

Cauda Equina

PROCEDURE	CONSERVATIVE	Clinical Findings		
	CARE	SUBJECTIVE	OBJECTIVE	IMAGING
LUMBAR: LAMINECTOMY, DISCECTOMY,	Not Applicable	Sudden onset or rapid progression of sensory symptoms **AND**	Acute Progressive neurological deficit that is either bilateral or involves multiple neurological levels **AND**	Demonstrates a large lesion producing central stenosis with tight obstruction Tests include: CT Scan OR MRI OR Myelogram

Reference: Provider Bulletin 91-01; Date Introduced: Jan. 91'

Criteria for Knee Surgery

PROCEDURE	Clinical Findings		
	SUBJECTIVE	**OBJECTIVE**	**IMAGING**
ANTERIOR CRUCIATE LIGAMENT (ACL) REPAIR	(Pain alone is not an indication) **AND** Instability of the knee; described as "buckling or giving way" --- Supportive findings: Significant effusion at the time of injury AND/OR Description of injury indicates a rotary twisting or hyperextension occurred	Positive Lachman's sign --- **AND** Supportive findings: Positive pivot shift AND/OR Positive anterior drawer AND/OR Positive KT 1000 >3-5 mm = +1 >5-7 mm = +2 >7 mm = +3	Positive findings with: Arthrogram OR MRI OR Arthroscopy
PATELLA TENDON RE-ALIGNMENT OR MAQUET PROCEDURE	Rest-sitting pain **AND**	Pain with patellar/ femoral movement **AND** AND/OR Recurrent dislocations	Recurrent effusion AND Patella apprehension AND Synovitis with or without crepitus AND Lateral tracking AND Increased Q angle>15 degrees
KNEE JOINT REPLACEMENT	Limited range of motion **AND** AND Night pain of the joint AND No relief of pain with conservative care	Significant loss or erosion of cartilage to the bone **AND**	Positive findings with Sanding films OR Arthroscopy
(If 2 of the 3 compartments are affected, a total joint replacement is indicated. If only 1 compartment is affected, a unicompartmental or partial replacement is indicated.)			

Reference: Provider Bulletin 91-01; Date Introduced: Jan. 91'

Criteria for Cervical Surgery
Related to Entrapment of a Single Cervical Nerve Root

PROCEDURE	CONSERVATIVE CARE	Clinical Findings: SUBJECTIVE	OBJECTIVE	IMAGING
CERVICAL LAMINECTOMY DISCECTOMY LAMINOTOMY FORAMINOTOMY WITH OR WITHOUT FUSION, EXCLUDING FRACTURE	6-8 weeks minimum For example: • physical therapy • non-steroid anti-inflammatory agents • cervical traction	**AND** Sensory symptoms in a dermatomal distribution (could include: radiating pain, paresthesia, tingling, burning or numbness)	**AND** Dermatomal sensory deficit OR Motor deficit OR Reflex changes OR Positive EMG	**AND** Abnormal test results that correlate with the level of nerve root involvement consistent with subjective and objective findings. Tests include: CT scan OR MRI OR Myelogram

Cases to be referred to a physician advisor:

- Repeat surgery at same level
- Request for surgery at the C3-4 level
- Requests for surgery with signs and symptoms indicating myelopathy

When requesting authorization for decompression of multiple level nerve roots, each level is subject to the criteria.

Reference: Provider Bulletin 91-03; Date Introduced: May 91'

Criteria for Entrapment of a Single Lumbar Nerve Root

PROCEDURE	CONSERVATIVE CARE	Clinical Findings		
		SUBJECTIVE	OBJECTIVE	IMAGING
LUMBAR: LAMINECTOMY, LAMINOTOMY, DISCECTOMY, MICRO-DISCECTOMY, FORAMINOTOMY	Failure to improve with four weeks minimum. For example: • Physical therapy • Non-steroidal anti-inflammatory agents • Traction	**AND** Sensory symptoms in dermatomal distribution may include: Radiating pain, burning, numbness, tingling or paresthesia of lower extremity	**OR** Dermatomal sensory deficit OR Motor deficit (eg, foot drop or quadriceps weakness) OR Reflex changes OR Positive EMG	**AND** Abnormal test results that correlate with the level of nerve root involvement consistent with subjective and objective findings. Tests include: CT Scan OR MRI OR Myelogram

Requests for authorization to treat lateral or central spinal stenosis not accompanies by nerve root entrapment or the necessity of arthrodesis will be reviewed by a Physician Adviser.

Reference: Provider Bulletin 92-01; Date Introduced: March 92 '

Criteria for Ankle/Foot

PROCEDURE	CONSERVATIVE CARE	Clinical Findings		
		SUBJECTIVE	OBJECTIVE	IMAGING
FUSION - ANKLE - TARSAL - METATARSAL TO TREAT NON- OR MAL-UNION OF A FRACTURE OR TRAUMATIC ARTHRITIS SECONDARY TO ON THE JOB INJURY TO THE AFFECTED JOINT	Immobilization which may include: - casting, bracing, shoe modification or other orthotics OR Anti-inflammatory medications	**AND** Pain including that which is aggravated by activity and weight-bearing AND Relieved by Xylocaine injection	**AND** Malalignment AND Decreased range of motion	**AND** Positive x-ray confirming presence of: - Loss of articular cartilage (arthritis) OR - Bone deformity (hypertrophic spurring, sclerosis) OR - Non or mal-union of a fracture Supportive imaging could include: Bone scan (for arthritis only) to confirm localization OR MRI OR Tomography

- Requests for intertarsal or subtalar fusion will be referred to Physician Adviser

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Reference: Provider Bulletin 92-01; Date Introduced: Mar. 92'

Criteria for Ankle Continued

PROCEDURE	CONSERVATIVE CARE	Clinical Findings		
		SUBJECTIVE	OBJECTIVE	IMAGING
LATERAL LIGAMENT ANKLE RECONSTRUCTION FOR CHRONIC INSTABILITY OR ACUTE SPRAIN/STRAIN INVERSION INJURY	Physical Therapy - immobilization with support coast or ankle brace - Rehab program For either of the above, time frame will be variable with severity of trauma	For chronic: **AND** - Instability of the ankle Supportive findings: - Complaint of swelling For acute: - Description of an inversion AND/OR Hyperextension injury, ecchymosis, swelling	For chronic: **AND** Positive anterior drawer For acute: - Grade 3 injury (lateral injury) AND/OR Osteochondral fragment AND/OR Medial incompetence AND Positive anterior drawer	Positive stress x-rays identifying motion at ankle or subtalar joint. At least 15° lateral opening at the ankle joint. OR Demonstrable subtalar movement AND Negative to minimal arthritic joint changes on x-ray

- Requests to use prosthetic ligaments will not be authorized

- Requests for any plastic implant will be referred to a Physician Adviser for review

- Requests for calcaneous osteotomies will be referred to a Physician Adviser for review

Criteria for MRI of the Lumbar Spine

INDICATIONS FOR MRI OF THE LUMBAR SPINE

- Any neurologic deficit, evidence of radiculopathy, cauda equina compression (e.g., sudden bowel/bladder disturbance).

OR

- Suspected systemic disorder, i.e., to r/o metastatic or infectious disease.

OR

- Localized back pain with no radiculopathy (leg pain), clinical history of lumbar sprain or strain, and failed 6 week course of conservative care.

INDICATIONS FOR REPEAT MRI OF THE LUMBAR SPINE

- Significant change in clinical finding, i.e., new or progressive neurological deficit.

NOTE: The primary physician is strongly encouraged to coordinate with a subspecialist: i.e., a board certified spine specialist, orthopedist or radiologist, before ordering a repeat MRI of the lumbar spine.

Reference: Provider Bulletin 94-07; Date Introduced: Jan. 94'

Criteria for Shoulder Surgery

PROCEDURE	CONSERVATIVE CARE	Clinical Findings		
		SUBJECTIVE	OBJECTIVE	IMAGING
ROTATOR CUFF REPAIR Cervical pathology and frozen shoulder syndrome should be ruled out prior to the request _____ Arthroscopy prior to open surgery is indicated in certain pathological circumstances subject to review	Failure to improve with outpatient therapy and conservative care: • Acute case 1 to 3 weeks • Erosive case: 3 to 6 months* • Three months of conservative care is adequate if treatment has been continuous; six months applies to those cases in which treatment has been intermittent	Severe shoulder pain and inability to elevate the arm	Weak or absent abduction. May also demonstrate atrophy AND Tenderness over rotator cuff area AND Temporary pain relief obtained with injection of anesthetic	Conventional x-rays, AP, and true lateral or axillary view. AND Arthrogram with positive evidence of deficit in rotator cuff OR Positive findings on previous arthroscopy, if performed
ANTERIOR ACROMIONECTOMY ACROMIAL IMPINGEMENT SYNDROME	Failure to improve with 4-6 months of Failure to improve with 4-6 months of conservative care.	Pain with active are motion 90 to 130 degrees AND Pain at night	Positive impingement test and relief of pain with anesthetic injection (Tenderness in the anterior acromial area may also be present)	Conventional x-rays, AP,and true lateral or axillary view. Additional coracoacromial views may be required
REPAIR OF AC OR CC LIAGAMENTS-ACROMIO-CLAVICULAR SEPARATION MOST WILL DO WELL WITH CONSERVATIVE SUPPORTIVE CARE		Pain with marked functional difficulty in use	Marked deformity	Conventional x-rays: A grade III+ separation
MUMFORD PROCEDURE EXCISION OF DISTAL CLAVICLE-ACROMIO-CLAVICULAR SEPARATION	Failure to improve with extended period of conservative care	Pain at AC joint; aggravation of pain with motion of shoulder or carrying weight	Prominent distal clavicle AND/OR Pain relief obtained with an injection of anesthetic for diagnostic therapeutic trial	Complete or incomplete separation of AC joint OR Severe DJD or post traumatic changes at AC joint noted on conventional films

_____

Reference: Provider Bulletin 94-07; Date Introduced: Jan. 94'

Criteria for Shoulder Surgery -- Continued

PROCEDURE	CONSERVATIVE CARE	Clinical Findings		
		SUBJECTIVE	OBJECTIVE	IMAGING
OPEN BANKART, BROSTPW. ETC. RECURRENT DISLOCATIONS Note: A second surgical opinion and psychiatric/ psychological evaluation will be obtained if this is the second request for this procedure	None	History of multiple dislocations that inhibit activities of daily living **AND** →		Must have conventional x-rays, AP and <u>true lateral</u> or axillary view
REPAIR OF BICEPS TENDON-PROXIMAL RUPTURE OF THE BICEPS 90% do not need repair Consideration of tenodesis should include the following: • Patient should be a young adult • Procedure should be done in conjunction with another open repair • There should be evidence of an incomplete tear	None	Complaint of more than "normal" amount of pain that does not resolve with attempt to use arm Pain and function fails to follow normal course of recovery	**AND** Classical Appearance of ruptured muscle	**AND** None
REPAIR OF BICEPS TENDON-DISTAL RUPTURE OF THE BICEPS All should be repaired within one week of injury or diagnosis. A diagnosis is made when the physician cannot palpate the insertion of the tendon at the patient's antecubital fossa.				
<u>SHOULDER ARTHROSCOPY FOR DIAGNOSTIC PURPOSES</u> This procedure is used primarily for diagnostic purposes when other imaging is inconclusive and acute pain or limitation of function continues despite conservative care. Shoulder arthroscopy should be performed in the outpatient setting. Requests for authorization of this procedure in the inpatient setting will be reviewed by a peer physician.				

Guidelines For Lumbar Fusion (Arthrodesis)

The following guidelines refer to low back pain and associated symptoms developing in the context of routine work activity, such as lifting or falling without evidence of spinal fracture. The guidelines will not apply to requests for fusion to treat a spinal fracture or dislocation.

A. Conservative Care

The patient should have at least three months of conservative therapy for low back pain, which may include use of anti-inflammatory medications, physical reconditioning, lumbar stabilization, manipulation therapy, or facet or epidural injections. The surgeon requesting the lumbar fusion should have personally evaluated the patient on at least two occasions prior to requesting the fusion. Clinical psychological or psychiatric assessment of all patients who have been on disability, and **who meet the following criteria**, would be required prior to lumbar fusion. This assessment should be directed at helping the requesting surgeon identify specific psychological risk factors for chronic disability that may be barriers to recovery following lumbar fusion surgery.

B. In The Patient With No Prior Spinal Surgery

1. Mechanical (non-radicular) low back pain with instability (as defined in D below)

OR

2. Spondylolisthesis with objective symptoms/signs of neurogenic claudication or of unilateral or bilateral radiculopathy symptoms/signs corroborated by neurologic examination and by MRI or CT (with or without myelography) or with instability (as defined in D below).

C-1. If A Fusion Is Requested At A Level On Which A Previous Laminectomy, Diskectomy, Or Other Decompressive Procedure Has Been Done, the patient should meet the following criteria:

Reference: Provider Bulletin 98-05; Date Introduced: Jun. 98'

1. Mechanical (non-radicular) low back pain **with instability** (as defined in Section D below) at the same or adjacent levels,

OR

2. Mechanical (non-radicular) low back pain with psudospondylolisthesis, rotational deformity or other condition leading or progressive (measurable) deformity.

OR

3. Objective signs of neurogenic claudication or bilateral lumbar radiculopathy, confirmed by MRI or CT/myelography and by detailed clinical neurological examination or neurological/neurosurgical consultation.

C-2 If A Fusion Is Requested At A Level That Has Already Been Fused, There Must Be:

1. Objective evidence (e.g., abnormal CT scan) of pseudarthrosis,

OR

2. Objective signs of neurogenic claudication or bilateral lumbar radiculopathy, confirmed by MRI or CT/myelography and by detailed clinical neurological examination or neurological/neurosurgical consultation.

C-3 If A Fusion Is Requested At A Level Adjacent To One That Has Previously Been Fused, the patient should meet criteria given in Section B above.

D. Definition Of Instability

Instability of the lumbar segment is defined as at least 4mm of anterior/ posterior translation at L3-4 and L4-5, or 5mm of translation at L5-S1 or 11 degrees greater end plate angular change at a single level compared to an adjacent level on adequate flexion/extension films.

E. Relative Contraindications To Lumbar Fusion (Applicable Only If Patient Meets Criteria B, C1, C2, Or C3)

✓ Severe physical de-conditioning

✓ Current smoking

- ✓ Multiple level degenerative disease of the lumbar spine
- ✓ Obesity (>120% of ideal body weight)
- ✓ At least 12 months of disability (time-loss) prior to consideration of fusion
- ✓ No evidence of functional recovery (return to work) for at least six months following the most recent spine surgery
- ✓ Psychosocial factors that are correlated with poor outcome, such as:
  - History of substance abuse (drug or alcohol)
  - High degrees of somatization on clinical or psychological evaluation
  - History of major psychiatric illness prior to injury
  - Current evidence of factitious disorder

F. Associated Requirements For Lumbar Fusion

1. The physician should discuss the following information with the patient prior to surgery and a detailed information form memorializing the discussion should be signed by the patient and physician (see attached example). The contract reviewer will confirm that the information form incorporates the following language and that the form has been signed.

   - The chances of an injured worker being off disability 2 years after lumbar fusion are only 32%.
   - More than 50% of workers who received lumbar fusion in Washington Workers' Compensation felt that both pain and functional recovery were no better or worse after lumbar fusion.
   - The overall rate of re-operation within 2 years for all fusions is approximately 23%.
   - Smoking at the time of fusion greatly increases the risk of pseudarthrosis.
   - Pain relief, even when present, is not likely to be complete.

2. The operating surgeon should follow-up the patient undergoing lumbar fusion at least every two months for the first six postoperative months, and at least every six months for the ensuing two years.

G. Additional Comments

1. Lumbar fusion is not indicated with an initial laminectomy/discectomy related to unilateral compression of a lumbar nerve root.

2. Although adding to the clinical data base, provocative discography, diagnostic facet joint injections, and pain relief during the use of a rigid spinal brace are not definitive indications for fusion.

3. All intraoperative determinations of instability that lead to fusion must be clearly documented at the time, and (if requested by L&I) subsequently discussed with a peer surgeon.

4. All requests for 360° fusion should be reviewed by a physician consultant.

Lumbar Fusion Patient Information Form

(To be reviewed with your physician)

The department has developed guidelines for various surgical procedures as part of its utilization management program. The guidelines for lumbar fusion require that your physician discuss the following information with you prior t surgery:

A recent study* at the University of Washington showed that in Washington workers:

- The chances of an injured worker being off of disability timeloss 2 years after fusion are 32%.
- More than 50% of workers who received lumbar fusion, in Washington Workers' Compensation, felt that both pain and functional recovery were no better or worse after lumbar fusion.
- The overall rate of re-operation within 2 years, for all fusions, is approximately 23%. The use of instrumentation in Washington workers nearly doubled the risk for re-operation.

In addition:

- Smoking at the time of fusion greatly increases the risk of fusion failure.
- Pain relief after fusion, even when it occurs, is not likely to be complete.

My physician has discussed this information with me. I understand it and wish to proceed with the fusion. I understand that this information does NOT take the place of, and is separate and distinct from, the operative consent form that I will review prior to surgery.

_____ _____

Patient Physician

___/___/___ ___/___/___

Date Date

***** Gary Franklin, MD, et. al., "Outcomes of Lumbar Fusion in Washington State Workers' Compensation" SPINE 1994, Vol 9, No. 17, pp. 1897 – 1903.

Surgery for Thoracic Outlet Syndrome (TOS)

TYPE OF TOS	SUBJECTIVE		OBJECTIVE		IMAGING
VASCULAR TOS ARTERIAL	At least **three** of the following must be present in the affected upper extremity: A. Pain B. Swelling or heaviness C. Decreased temperature or change in color D. Paresthesias in the ulnar nerve distribution	**AND**	At lease **one** of the following: A. Pallor or coolness B. Gangrene of the digits in advanced cases	**AND**	C. Abnormal arteriogram
VASCULAR TOS VENOUS	At lease **three** of the following must be present in the affected upper extremity: A. Pain B. Swelling or heaviness C. Decreased temperature or change in color D. Paraesthesias in the ulnar nerve distribution	**AND**	At least **two** of the following: A. Swelling of the arm, B. Venous engorgement C. Cyanosis	**AND**	D. Abnormal venogram
NEUROGENIC TOS	In the affected upper extremity: A. Pain ***and*** B. Numbness or paresthesia in the ulnar nerve distribution	**AND**	In the affected upper extremity, **all of the** following electrodiagnostic abnormalities must be found: A. Reduced amplitude median motor response ***and*** B. Reduced amplitude ulnar sensory response ***and*** C. Denervation in muscles innervated by lower trunk of the brachial plexus		

*1 The clinical findings in TOS may be similar to those in carpal tunnel syndrome, ulnar neuropathy or cervical radiculopathy. A physician should consider these alternative diagnoses before requesting TOS surgery.

2. Most patients with TOS have cervical ribs.

3. The Department of Labor and Industries has recently concluded a retrospective study of outcomes of thoracic outlet surgery on patients with Labor and Industries claims. The results indicate that long-term outcomes after TOS surgery are worse than outcomes with medical management of TOS.

SEE NEXT PAGE FOR DETAILS OF CRITERIA

Reference: Provider Bulletin 95-04; Date Introduced: April 95'

Criteria For The Electrodiagnostic Diagnosis Of Unilateral Neurogenic Thoracic Outlet Syndrome (TOS)^^

All 3 of the following criteria must be found in the affected limb:

1. Amplitude of median motor response is reduced
   And
2. Amplitude of ulnar sensory response is reduced
   And
3. Needle exam shows denervation in muscles innervated by lower trunk of brachial plexus.

Details Regarding the Above Noted Criteria:

Criterion #1

a) Using standard surface electrodes with active pick up over the abductor pollicis brevis, the amplitude of the median motor response on the affected side should be less than 50% of that obtained on the unaffected side.

Criterion #2

a) Using standard ring electrodes on the fifth digit, the ulnar sensory amplitude on the affected side should be less than 60% of the amplitude on the unaffected side.

Criterion #3

a) Muscles innervated by the lower trunk of the brachial plexus include the abductor pollicis brevis, pronator quadratus, flexor pollicis longus, first dorsal interosseous, abductor digiti minimi, flexor carpi ulnaris, extensor pollicis brevis, and extensor indicis.

b) EMG abnormalities in TOS are most commonly seen in median and ulnar innervated intrinsic muscles of the hand -- especially the abductor pollis brevis.

c) Positive waves and fibrillations may be found, but chronic denervation changes are more common -- that is, increased motor unit amplitude, increased motor unit duration, and decreased recruitment with rapid firing of motor units are activated.

Notes

The electromyographer should rule out neuropathic conditions that might mimic TOS, specifically cervical radiculopathy, carpal tunnel syndrome, ulnar neuropathy and polyneuropathy.

^^Abstracted from Wilbourn A.J. American Association of Electromyography and Electrodiagnosis. Case Report #7: True Neurogenic Thoracic Outlet Syndrome. 1992.

Diagnoses and Treatment of Work-Related Carpal Tunnel Syndrome (OCTS)

These guidelines are to be used by physicians and Labor and Industries claim managers.

SECTION 1 -- CLAIM ACCEPTANCE

In general, both appropriate symptoms and signs and work relatedness should be present for Labor and Industries to accept a claim as OCTS. Nerve conduction velocity testing (NCVs) is not necessary for claim acceptance except in questionable circumstances.

A. Symptoms and Signs

Appropriate symptoms would include, numbness, tingling or burning pain of one or both hands, especially noted after work and at night. These nocturnal symptoms are prominent in 50-70% of patients. Patients frequently awaken at night or early morning and shake their hands to rid themselves of these symptoms. The location of these symptoms may be in the entire hand or localized to the thumb and first two or three fingers. If the nerve symptoms are prominent only in the fourth and fifth fingers (ring and little fingers), a different diagnosis (e.g., ulnar neuropathy) should be considered. Although burning pain is often prominent in the hands and palm side of the wrists, an aching pain may radiate (be felt in) to the medial elbow region or more proximally to the shoulder.

Findings on physical examination (signs) are frequently absent or non-specific. Tinel's sign (tapping on the wrist or over the median nerve) and Phelan's signs (forced flexion of the wrist) are frequently described, but by themselves are not specifically diagnostic of OCTS. Their presence merely corroborates the presence of other clear neurologic symptoms.

Other signs are more specific and include decreased sensation to pin or light touch in the palm and first three digits or weakness or atrophy of the muscles of the thenar eminence (especially the abductor pollucis brevis). The presence of the latter signs (but not Tinel's or Phelan's) may suggest more acute or advanced nerve injury and perhaps the need for more aggressive treatment.

In general, symptoms are better when not working and on holidays when the worker has been removed from the workplace exposure. Non-specific symptoms, (e.g., pain without numbness, tingling or burning; "dropping things") should not be considered for the diagnosis of OCTS.

Reference: Provider Bulletin 95-10; Date Introduced: Nov. 95'

B. Work-relatedness

Any activity requiring extensive or continuous use of the hands in work may be an appropriate exposure. In general, one of the following work conditions should be occurring on a regular basis:

1) Repetitive hand use, especially for prolonged periods (e.g., keyboard users), against force (e.g., meat cutters) or with awkward hand positions (e.g., grocery checkers), with repeated wrist flexion, extension or deviation as well as forearm rotation, or with constant firm gripping.

2) The presence of regular, strong vibrations (e.g., jackhammer, chainsaw).

3) Regular or intermittent pressure on the wrist. (Note: acute carpal tunnel syndrome may be associated with acute trauma, i.e., fracture, crush injury of wrist, etc.).

The types of jobs that are most frequently mentioned in the literature or reported in L&I's data include: meat cutting; seafood, fruit, or meat processing or canning; carpentry; roofing; dry walling; boat building; book binding; wood products work; dental hygienist; and intensive word processing. This is not an exhaustive list. It is only meant to be a guide in consideration of work- relatedness. If the history of exposure is unclear, then speaking directly with the employer or claimant, or doing a walk through, to obtain more detailed information on job duties would be critical.

NERVE CONDUCTION TESTING (NCVs)
It is critical to obtain NCV testing in the following situations:

1. The attending physician's diagnosis is OCTS, but the clinical criteria (appropriate neurologic symptoms and/or signs) described above are not met.
2. The patient has been on time-loss for OCTS for more than two weeks and the clinical criteria are met.
3. Carpal tunnel decompression surgery is requested.

Conceptually, validation of the clinical diagnosis of OCTS depends on the finding of sequential slowing of sensory and/or motor fibers of the median nerve across the carpal tunnel.

The most useful nerve conduction tests with their ***(upper limit of) normal cut-points*** are as follows:

Median motor distal latency	4.5 msec (slowing would be longer, i.e., greater than 4.5 msec)
Median sensory distal latency	wrist-digit II (14 cm)=3.5 msec palm-wrist (8 cm)=2.2 msec
Median-ulnar sensory latency difference	finger-wrist difference (14 cm)=0.5 msec palm-wrist difference (8 cm) =0.3 msec

These upper limit cut points are derived from published literature. If the electromyographer performs non-conventional tests for OCTS not listed here, normal values should have been established in that physician's laboratory.

Labs can use their own cut points if they have adequately established their own normal values.

In all cases, and particularly in cases with borderline NCV results, control for skin temperature should be documented. In general, the above referenced values will hold for skin temperature in the range of 30-34 degrees Centigrade. Lower temperatures will be associated with falsely slowed NCV results.

An electromyogram (EMG), or needle examination of the muscles supplied by the median nerve, may be useful in documenting actual nerve damage (axonal loss). This test should be done especially in cases with sensory loss, weakness or muscle atrophy in the median nerve distribution.

TREATMENT

A. Conservative treatment

Conservative management may be helpful and may include:

1) Splinting of the wrist. (May be more useful at night).

2) Anti-inflammatory medication including non-steroidal.

3) Steroid injections - although this form of treatment is favored by some physicians, it may not have long term benefits and may itself cause nerve injury. No more than ***two steroid injections over a three-month period*** will be authorized.

The duration of conservative treatment will primarily depend on whether the patient can remain at work. Most patients will improve when off work, whether or not specific treatment is rendered. In some cases, job modification, along with conservative treatment, may improve symptoms and prevent worsening of OCTS. If job modification is not possible, or if the claimant cannot continue working with conservative treatment, then surgery should be considered as a treatment option.

B. Surgery

Decompression of the transverse carpal ligament is the surgical procedure of choice for OCTS. A second procedure, internal neurolysis, or freeing up of the nerve, is sometimes requested; however, there is no evidence to suggest that this procedure is necessary and, in most cases, requests for this procedure will be denied. Questions about this procedure should be referred to the department's orthopedic consultant by calling (360) 902-5026.

In general, the following criteria should have been met for authorization of surgery to occur:

1. The clinical history should be consistent with OCTS.

2. NCVs should have demonstrated a conduction slowing of the median motor or sensory fibers across the carpal tunnel.

3. A course of conservative management must have been tried.

Most studies suggest that in 60-90% of the post-surgical cases the burning pain associated with OCTS will be alleviated. The patient's ability to return to the same job is not clear. If pain persists or recurs, NCVs can help sort out whether nerve entrapment continues to be a problem.

SPECIAL CASES

Questions may arise in several specific situations that may raise questions about the validity of the claim for OCTS or about the need for surgery.

A. Work-relatedness may not be obvious. Some work exposures do not meet the guidelines for work-relatedness. If there is a question about the job exposure and whether such exposure could cause OCTS, the claim manager should refer the case to the occupational medical consultant by calling (360) 902-5026.

B. Surgery may be requested in those injured workers whose clinical picture and work relatedness is quite clear, but whose NCVs are normal. Most clinicians agree that a minority (<10%) of patients with clinical OCTS may have normal NCVs. Options here may be the following:

    1. Were the most sensitive and specific NCV tests done (e.g., palm-wrist median sensory latency)? If not, request that they be done.

    2. If the NCVs were done after a period of not working, previously abnormal NCVs may have returned to normal. It would be reasonable in these cases to suggest that the claimant return to work for a brief time (a few days to a week) and repeat NCVs while they are still working.

C. If OCTS is not documented by clinical criteria and NCV testing, other clinical problems related to repetitive use (i.e., tendonitis) should be investigated and treated appropriately. It would also be important to rule out other neurologic causes of tingling in the hands. Referral to an appropriate specialist (neurologist, physiatrist) would be prudent in such cases.

D. Carpal tunnel syndrome may also be caused by anything that decreases the cross-sectional area of the carpal tunnel or adds to the volume of the carpal tunnel, resulting in increased pressure on the median nerve. This could occur by distortion of the bones or ligaments by fracture or crush injury of the forearm or hand associated with generalized or chronic swelling (edema).

E. Carpal tunnel syndrome may be associated with other chronic conditions that may cause nerve damage or predispose a nerve to injury from compression. The most common of these conditions is diabetes. The key test here is whether, in spite of the presence of such condition, the symptoms of OCTS can be documented to have begun only after beginning work at the job in question.

F. A predisposing, physiological condition is pregnancy, wherein increased plasma volume increases pressure within the carpal tunnel. In such cases, symptoms universally disappear immediately after birth. If they do not, other etiologies (e.g., work-related, diabetes) should be pursued.

RETURN TO WORK AFTER OCTS SURGERY

The vast majority of persons with work-related OCTS are expected to have dramatic relief of their symptoms after carpal tunnel decompression surgery and should return to their same job. Return to work, with or without job modification, should be tried in most people. If symptoms worsen or reappear after return to work, repeat NCVs will help to sort out if OCTS has recurred, and if surgery successfully removed the pressure on the median nerve (NCVs will improve with successful surgery, although they may not return completely to normal).

Criteria for the Diagnosis and Treatment of Work-Related Carpal Tunnel Syndrome				
PROCEDURE	**CONSERVATIVE CARE**	**Clinical Findings**		
		SUBJECTIVE	**OBJECTIVE**	**DIAGNOSTIC**
DECOMPRESSION OF THE MEDIAN NERVE	● Splinting **AND** ● Anti-inflammatory medication ● Steroid injections* * No more than 2 injections in 3 months NOTE: In the absence of conservative care or with minimal conservative care, a request for surgery can still be considered pending clinical findings.	● Complaints of numbness, tingling, **OR** or "burning" pain of the hand or thumb and first 2 fingers. Nocturnal symptoms may be prominent NOTE: Pain may radiate to inner elbow or to the shoulder	● Decreased sensation to pin **AND** in palm and first 3 digits OR ● Weakness or atrophy of the thenar eminence muscles.	● Abnormal nerve conduction studies. Any one abnormality in one of the following*. ● Median motor distal latency >4.5 msec ● Median sensory distal latency wrist digit II (14 cm) >3.5 msec palm-wrist (8 cm) >2.2 msec ● Median-ulnar sensory latency finger-wrist difference >0.5 msec palm-wrist difference >0.3 msec OR ● Positive Needle EMG in cases of definite sensory deficit in median nerve distribution or weakness/ atrophy of the thenar muscle NOTE: If text result borderline, may want to repeat after (attempts to) RTW. *NCV must be done with control for skin temperature. Values are true for temperature in range of 30-34 C.
	Nerve conduction studies should be done if worker is off work for > than two weeks or surgery requested.			

SECTION 2 -- NEEDLE ELECTROMYOGRAPHY IN THE DIAGNOSIS OF CARPAL TUNNEL SYNDROME

Needle electromyography has only a limited role in the electrodiagnostic evaluation of carpal tunnel syndrome. It should generally not be done if nerve conduction studies are normal. There are three circumstances in which it would be reasonable to do needle electromyography during an evaluation for carpal tunnel syndrome:

a. Nerve conduction studies are abnormal in a manner indicating carpal tunnel syndrome, and the patient demonstrates wasting or clinical weakness of the thenar muscles.

b. The electromyographer suspects that a neuropathic process other than (or in addition to) carpal tunnel syndrome exists (e.g., diabetes).

c. There is a history of an acute crush injury or other major trauma to the distal upper extremity.

SECTION 3 -- WORKSHEET FOR CARPAL TUNNEL SYNDROME ELECTRODIAGNOSTIC STUDIES

DOCTORS PLEASE NOTE: This worksheet should accompany, BUT NOT REPLACE, the detailed report normally submitted to the department.

1. The purpose of this worksheet is to help medical consultants at L&I interpret electrodiagnostic testing that you do on L&I patients. It is for this reason that the worksheet follows on distal latency. The worksheet should be used only when the main purpose of your study is to evaluate a patient for OCTS.

2. You may have an automated system for reporting electrodiagnostic results. Feel free to send this in. But the department's worksheet should also be filled out and submitted.

3. On the worksheet, sensory distal latency should be measured to response peak and motor distal latency should be measured to response onset.

4. It is not necessary to do all the conduction studies listed on the worksheet. You should do only the studies needed to rule OCTS in or out.

5. It is sometimes necessary to do electrodiagnostic tests other than ones listed on the worksheet. If you do any additional studies bearing on the diagnosis of OCTS, please write them in the blank area below the listed studies.

6. If the inching technique of Kimura is used, only a maximum latency difference between 1 cm segments of 0.5 msec will be accepted as specific enough to corroborate the presence of OCTS.

7. The value of other studies of median nerve function has not been proven. These tests are NOT recommended for the diagnosis of OCTS. The following quotation is taken from a literature review published in Muscle & Nerve, 1993, Vol. 16, p. 1392-1414:

   > "Several other variations on median sensory and motor NCS's have been reported to be useful for the evaluation of patients with OCTS. The committee's review of the literature indicated that the value of these tests for the clinical electrodiagnostic evaluation of patients with OCTS remains to be established. These electrodiagnostic studies include the following: (1) studies of the median motor distal latency recorded from the lumbrical muscles,.. (2) measurement of the refractory period of the median nerve,... (3) median motor residual latency measurements,... (4) terminal latency ratio,... (5) median F-wave abnormalities,... (6) median motor nerve conduction amplitude comparisons with stimulation above and below the carpal ligament,... (7) anterior interosseous/median nerve latency ratio,... (8) change in median motor response configuration with median nerve stimulation at the wrist and elbow in the presence of Martin-Gruber anastomosis,... (9) sensory amplitude measurements,... and (10) measurement of median sensory and motor nerve conduction across the wrist before and after prolonged wrist flexion."

The Washington State Medical Association (WSMA) Medical Treatment Guidelines Subcommittee and the Department of Labor and Industries Office of the Medical Director endorses the opinions in the above quote and believes that electromyographers should act in accordance with these opinions.

Worksheet for Carpal Tunnel Nerve Conduction Studies

	Abnormal cut-point	Right Arm Distal Latency (msec)	Left Arm Distal Latency (msec)
1. Median motor to APB	>4.5 msec		
2. Median sensory over 14 cm (wrist to digit 2 or 3)	>3.5 msec		
3. Median sensory over 8 cm (transcarpal)	>2.2 msec		
4. Median sensory to Digit 4 MINUS Ulnar sensory to Digit 4	>.5 msec		
5. Median sensory (transcarpal) MINUS Ulnar sensory (transcarpal)	>.3 msec		
6. Ulnar sensory to Digit 5	>3.6 msec		

Claim Number: _____

Claimant Name: _____

Additional Comments:

_____

_____

_____

_____

_____ _____

Signed Date

TO: **Psychiatrists and Psychologists**

FROM: Washington State Medical Association Medical Treatment Guidelines Subcommittee of the WSMA Industrial Insurance & Rehabilitation Committee

and

The Department of Labor and Industries Office of the Medical Director

DATE: November 1, 1995

SUBJECT: ***Guidelines for Psychiatric and Psychological Evaluation of Injured or Chronically Disabled Workers*****

Enclosed you will find a set of suggestions for conducting psychiatric or psychological evaluations of injured workers with chronic pain problems. The suggestions focus on the clinical interview. They identify issues to explore and describe difficulties that frequently arise in evaluating injured workers.

The suggestions were developed for the specific problem of assessing low back pain patients being considered for spinal fusion. Psychological or psychiatric evaluation is required in this setting; that is, *the Department of Labor and Industries does not authorize a lumbar spinal fusion unless the patient has undergone a psychological or psychiatric evaluation*. The WSMA Medical Treatment Guidelines Subcommittee believes that although the suggestions were developed in a very specific context, they could help psychiatrists or psychologists perform elective evaluations of injured workers with a wide range of problems.

The suggestions are being sent to all psychiatrists and psychologists who are Labor and Industries' providers. We hope you will find them useful. Feel free to incorporate the suggestions you find useful into future psychological/psychiatric evaluations.

***** *These guidelines were developed by Labor and Industries in collaboration with the WSMA Medical Treatment Guidelines Subcommittee of the WSMA Industrial Insurance and Rehabilitation Committee.*

Guidelines for Psychiatric and Psychological Evaluation Of Injured or Chronically Disabled Workers

GENERAL

A psychiatric interview can seem threatening to injured workers. They may fear they were sent for evaluation because their doctors or claim managers suspect their conditions are "made up" or "all in their head." Some perceive their industrial claim as a struggle and enter the examination expecting to be discounted. Despite these difficulties, a respectful, patient, and empathic interviewer can learn a great deal. Patients with chronic disability are often in crisis and may be eager to relate their histories if we respond favorably to initial fear and defensiveness.

The purpose of the evaluation may vary, but commonly there are two issues you will be asked to address:

- Is a psychiatric condition present? Responding to this question involves a diagnosis centered assessment compatible with DSM-IV.

- Are there emotional factors that perpetuate physical complaints? These factors may be disorders on Axis I or Axis II, or may be subtle features that by themselves would not result in a psychiatric diagnosis. Subtle factors include unspoken fears, hidden motives, or family dysfunction. This is the more difficult part of the examination, for which experience with chronic disability is helpful. Psychiatric features that commonly contribute to chronic disability include agoraphobia, antisocial and dependent personality traits, perception of harassment at work, and threatened abandonment. Often the dynamic involves a central emotional vulnerability concealed by a screen of disability and physical complaints. To arrive at an understanding of the underlying issue, we will need heightened sensitivity to common patterns in chronic disability. This report provides some suggestions for those who wish to understand these issues.

The Clinical Interview Using DSM-IV published by the American Psychiatric Association describes two interview styles: symptom-oriented or descriptive and insight-oriented or psychodynamic. A symptom-oriented style searches for characteristic signs and symptoms of disorders in DSM-IV and is useful approaching the first question. The second is non-directive and allows examination of unconscious communication. Aspects of both styles are useful in the interview of injured workers.

Reference: Date Introduced: November 1995

As with the insight-oriented style, the interviewer should avoid leading questions. If the person is suggestible or dramatizes illness, questions that infer diagnostic criteria yield positive responses in many categories. For example, with depression, it is better to ask if there has been a change in energy, rather than if energy is low.

Consistent with the symptom-oriented style, it is helpful to provide structure at appropriate times during the interview. Allowing the patient to relate history without direction, though sometimes desirable in psychotherapy, can result in a shallow, uninformed report. It is important to explore symptoms thoroughly in a non-leading way, rather than accept complaints at face value. To become aware of hidden fears or motives, the interviewer must sometimes actively pursue clues from the interview or the file.

Medical Records

Another area of importance is review of medical records. Records from before the injury can be particularly important. As you review medical records be alert for several features. First, be aware of "functional findings" or signs that are inconsistent with organic illness, as described below. Second, assess attitude toward treatment and the medical and vocational system. If there is a recurrent pattern of passive resistance to all forms of treatment, there is reason to suspect psychological factors contribute to the disability. Third, look for evidence of substance abuse.

Functional findings include:

- Waddell's criteria for assessment of low back pain:
  a) Diffuse tenderness, especially to light touch.
  b) Inconsistent direct versus indirect observation, such as discrepancy of straight leg raising, sitting and supine.
  c) Pain on truncal rotation.
  d) Pain on axial compression.
  e) An abnormal degree of verbal or nonverbal pain behavior such as wincing, groaning, dramatic limp, or dramatic tearfulness during physical examination.

- Non-anatomic sensory disturbance, such as glove or stocking hypalgesia.

- Give-way weakness.

If there are inconsistencies comparing history with information from the medical file, it may be informative to ask about the inconsistencies.

GUIDELINES

Confidentiality

Generally, the interview is not a dyad. There are other interested parties, and it is necessary to explain that information is not confidential. Because of this public framework, it can facilitate communication if you dictate the report during the interview.
The person is then aware what other parties will hear and may feel reassured if the report is accurate and empathic. Also, allowing correction of potential errors may further a sense of control and enhance disclosure.

Introduction

Introduce yourself and explain the circumstances of the interview. Explain who will have access to the report. Personal information will be asked about, but the person can freely choose not to respond if uncomfortable with doing so. If true, it may be helpful to explain that psychiatric assessment is commonly requested when a physical injury has become chronic or when complex surgery is being considered, and the request for evaluation does not necessarily infer anything more than that.

The report should identify age, race, date and nature of injury, and any specific concerns about the evaluation.

Chief Complaint

Obtain a list of symptoms and complaints, including physical problems.

Circumstances Prior to the Injury

A traditional format might collect information regarding present illness at this point. Many use this format with good results. However, clarifying life events that precede the injury affords a broader perspective when the interview progresses to present illness. In either case, the following points should be covered at some point in the interview.

- Employment:

  Security of employment: If recently employed, or if the nature of work is intermittent, ask the percentage of time employed over last few years, and the reason for periods of unemployment. Ask the reason for leaving earlier employment. Assess changes in the economy for the industry, for example, whether the company is still in business or whether layoffs were planned.

  Employment problems: This area is often fruitful, and should be carefully examined. Determine what the supervisors were like to work for, and if there was harassment or conflict with coworkers or supervisors. Determine how the person's work

performance was viewed by superiors, and if reprimands or complaints were filed by the person or the employer. Carefully assess for perceptions of harassment or discrimination.

Employment plans: Ask about career plans before the injury.

- Family relationships:

  Spouse: Ask age, health, and employment status of spouse, as well as length of relationship. Is the spouse disabled? How do they get along? Were they ever separated? If this (or any important relationship) was threatened, try to determine if disability might be a conscious or unconscious tool for stabilizing the relationship.

  Children: Ask ages, health status, who is at home, and if there have been any significant problems.

  Other Family: Ask about any other family with frequent contact. It is useful to know if there has been recurrent conflict or any major losses in the family.

- Activities: Ask how leisure time is spent, hobbies, avocational interests. Ask how the injury has affected pleasurable activities.

- Interpersonal Relationships: Assess patterns of isolation Vs socialization. Ask about friends, comfort in group situations, as well as comfort being alone. Is there capacity for intimacy and for communication of personal concerns?

History of the Injury

A thorough history of how the injury occurred can be informative, especially if it may have been emotionally traumatic or head injury is suspected. If the injury was traumatic, determine if PTSD symptoms are present. A non-leading way might be to ask if much time is spent thinking about the accident and how it feels to think about it. It is also important to know if there is anger, blame, or guilt regarding circumstances of the injury.

Elicit a history of important events subsequent to the accident, including medical treatment and effects on family, work and finances. Bankruptcy, eviction, foreclosure, or repossession can contribute to chronic disability.

Medical History

The report should include a brief history of treatment and response, with a focus on:

- Medical system: The relationship with doctors, vocational counselors, and others is an important clue to personality function and motivation. If there is a pervasive

pattern of being misunderstood and persecuted you might suspect character pathology is a block to recovery. Unrealistic blame, martyrdom and entitlement suggest a hidden desire to remain disabled.

- Results of Treatment: Determine the longitudinal course of the illness. Individuals with chronic disability usually report that no treatment has provided lasting benefit, and the illness has steadily worsened despite all treatment efforts. What you may discover in talking with individuals with chronic disability is a curious contradiction between verbal and other channels of communication. On the surface, there is a positive image of a strong desire to recover and return to work, but upon wading into this stream one becomes aware of a strong undercurrent in a different direction. This is difficult to describe, but often it appears as a discomfort with certain topics and a pattern of communicating through inference. For example, the desire for recovery is vague, lacking a specific plan beyond continuation of passive treatments. Persistence in asking about plans may lead to irritability. They often mention the opinions of others, usually health care professionals, who think they are disabled. If you ask for specific information hoping to better understand a particular symptom, you might receive instead an illustration of how severely life has been affected by the symptom. They imply inability to function unless the illness resolves. They may seem preoccupied with additional treatment, particularly surgery or other passive approaches, and demonstrate resistance to physical conditioning and work hardening. They may be critical of prior physicians who expected too high a level of functioning and seem more comfortable with doctors willing to validate disability indefinitely.

  A way to open this area of inquiry might be to ask what the person believes is the cause of the problem, and if they feel doctors have addressed the problem. Ask what they would like to see happen.

- Locus of Control: Is the person's role passive, waiting for others to restore function, or is the injury a personal setback that must be adjusted to.

Work Since the Injury

Obtain a chronological history of work since the injury, including the reason for any disruptions. How was the person welcomed upon return? Blame for the injury, demotion, or suspicion of malingering are very stressful and can contribute to chronic disability. Conversely, acceptance and patience aid recovery. Ask about employment plans. If the person does not feel able to work, determine which symptoms present a barrier. Ask if the employer is receptive, or if the person has looked for work, and if so, the result. What level of income/status is acceptable? What does the person envision two years from now?

Psychiatric History

In addition to a general assessment of psychiatric symptoms, determine how life has been affected by the injury and how the person has adjusted to the changes. Generally, it is best to allow an unstructured recitation of events since the injury.

Common psychiatric findings are depression and panic disorder.

For depression, ask how the person's mood or spirits have been. If there is depression, what seemed to be the precipitant? Obtain a description of what it was like at the lowest point. If there is evidence for mood disorder, develop a history of any diagnostic criteria. It is important to distinguish effects of pain. For example, if there is middle insomnia, were the awakenings spontaneous (consistent with major depression) or due to pain. What did the person do upon awakening? Getting up to walk and relieve stiffness or pain suggests awakening due to pain.

Similar differential inquiries are necessary for disturbances of appetite, energy, libido, and ability to experience pleasure.

Panic disorder is common enough in the general population, but it is very common in the population described by chronic disability. When panic attacks occur in individuals who have trouble expressing emotion or who feel shame regarding emotional symptoms, the presentation is likely to be one of pain rather than anxiety. Discovering the condition, however, can be difficult.

The most sensitive screening seems to be a careful assessment of current activities, which is also useful. Avoidance of the typical problem areas for agoraphobics such as grocery stores, shopping malls, crowds and driving raises the suspicion of agoraphobia. From there you might ask how the person feels in these situations, and what happens that creates discomfort. Additionally, you may ask if there have been any spells involving dizziness or heart or breathing symptoms. If screening questions are positive, develop a full DSM-IV history, especially for agoraphobia. If panic attacks were present, what did the person do or feel like doing when they occurred at work.

Narcotic and alcohol dependence are often found in chronic disability. It is often difficult to assess this issue without information from the medical file.

Current Activities

Ask how time is spent. Boredom, purposelessness, or severe physical limitations may lead to depression.

Secondary gain from the family should be assessed. It is useful to know how the family has responded, for example if they have been supportive or impatient. What are the responsibilities at home? Have family members become employed as a result of the

injury, or alternatively, have family members sacrificed employment or other activities to care for the person?

Past Psychiatric History

Ask about prior illness, carefully assessing for substance abuse; use of psychiatric medication; evidence of sociopathy such as arrests; and history of prior trauma such as combat that might lead to PTSD. Assess carefully for substance abuse, relying on potential clues from medical records as well as the clinical history.

Past Medical History

Determine response to any prior illnesses or injuries. Important clues may come from medical records. Determine whether there were long periods of disability. Ask about the emotional response to prior injuries.

Family History

In addition to asking about familial illnesses such as mood disorders, substance abuse, and anxiety disorders, determine whether family members have been disabled.

Personal History

The record should include a customary history of the person's life, with emphasis on factors that have bearing on chronic disability. Such factors include:

- Family structure: A childhood history of conflict, abuse, or deprivation correlates with chronic disability. Determine the number and health of siblings and whether the parents stayed together. Obtain a history of adults in the home. Ask if they have worked steadily. Ask about their health, listening carefully for history of chronic illness, agoraphobia, depression, hypochondriasis, somatization, illness of the same kind the patient experiences, or periods of disability.

  Ask about the relationship with adults, following affect carefully for cues. Helpful questions might include, "What was he [or she] like when you were a child?" "How did he relate with you?" "Did you feel loved?" It is important to determine if sexual, physical or verbal abuse, or episodes of abandonment were present. Determine if alcohol or drug abuse was present in parents. Are childhood memories contiguous? Was there acting out, which might suggest deprivation or abuse?

  If there are risk factors for abuse, ask about symptoms of PTSD such as dissociation, nightmares, flashbacks. History of abandonment, neglect, and parental indifference are important.

- Education: Ask for education level, grade point, any special education, honors, repeating or skipping classes. Learning disabilities, attention deficit disorder, or educational failures can contribute to shame and a perception of low worth in the job market, which can fuel chronic disability. If there seems to be a disparity between educational and occupational success, try to discover the reason.

- Marital history: Look for clues suggesting difficulty sustaining relationships or antisocial traits.

- Employment history: A history of menial, unrewarding, or excessively demanding work correlates with chronic disability. Vocational difficulty may be indicated by frequent job change, being fired, and aimlessness.

Mental Status Examination

As in a standard mental status examination, report general appearance, attitude, motor behavior, speech pattern, affective state, thought processes, perception, intellectual function, orientation, memory and judgment. In addition, describe pain behavior and genuineness.

Describe any personality traits which may influence chronic disability, such as:

- Lack of empathy or self-absorption, as in attitudes of entitlement or antisocial indifference.

- Alexithymia and globally deficient insight with rigid, irritable avoidance of emotion.

- Evasiveness and discomfort with specific questions. Emphasis on an "industrial" explanation for symptoms with minimization of other stressors.

- Repeatedly seeing oneself as a victim.

- Chronic anger, projection of blame, or passive-aggressive patterns of response.

- Dependent traits, such as submissiveness, undue anticipation of others' needs, impaired assertiveness, and excessive longing to feel loved.

- Histrionic traits, psychological naivete, and Pollyanna attitudes.

DSM-IV Diagnoses

Specify axes I, II, IV and V, with findings that lead to each diagnosis.

Conclusions

In addition to responding to referral questions, it is useful to include:

- Risk factors for chronic disability and barriers to recovery. Identify which barriers may be treatable and which will probably not be responsive.

- An assessment of psychological factors in this person's presentation of illness. Explain as clearly as possible how, if at all, the emotional condition may contribute to disability.

- Treatment recommendations. Treatment for psychiatric illness due to the injury might be indicated. If treatment is recommended, you may wish to make specific recommendations for the attending orthopedist or neurologist to consider. If treatment is recommended, try to estimate prognosis and a time-frame.

- Alternatively, the history might reveal psychological features that are primarily responsible for the disability. In that case, it may be necessary to assist in setting limits on medical services and disability status.

- Ability to Work. Some patients will have a psychiatric disorder that limits or prevents employment. Others will have a psychiatric condition that interferes with comfort or willingness, but ability to work is not affected. It is important to differentiate impaired motivation from impaired ability to work, and to communicate the difference in the report.

Guidelines For Outpatient Prescription Of Controlled Substances, Schedules II-IV, For Workers On Time-Loss

Developed by the Washington State Medical Association and the Washington State Department of Labor and Industries.
Adopted 1992 by the Washington State Medical Association Industrial Insurance and Rehabilitation Committee

INTRODUCTION

Purpose of the Guidelines

Repeated, long-term use of prescription controlled substances for chronic nonmalignant pain may be a factor in the development of long-term disability. This condition may be preventable if at-risk patients and practices are proactively identified and managed appropriately.

It is hoped that the prescribing guidelines listed below will lead to more accurate and timely identification of workers at risk for the development of long-term disability. These guidelines may also be a component of future intervention strategies aimed at preventing long-term disability.

Development of the Guidelines

These guidelines were developed by the Washington State Medical Association (WSMA) Industrial Insurance and Rehabilitation Committee and the Washington State Department of Labor and Industries. They are based on information from existing prescription guidelines, literature reviews, pharmacologic and medical references, seminars, interviews of experts, and consultations with physicians who have private practices in a wide variety of specialties.

Application of the Guidelines

The guidelines are intended for use in the management of chronic nonmalignant pain. Chronic nonmalignant pain is defined as pain persisting beyond the expected normal healing time for an injury, for which traditional medical approaches have been unsuccessful. Application of these guidelines is intended only for outpatient prescriptions of nonparenteral controlled substances. The nonparenteral routes of administration are considered the only acceptable routes for treating chronic nonmalignant pain in the Washington state workers' compensation system (WAC 296-20-03003).

It is recognized that the guidelines cannot apply uniformly to every patient. Also, the guidelines cannot be the sole determining basis for identifying patients at risk for a drug use problem or currently experiencing a drug use problem. Mere application of the guidelines cannot substitute for a thorough assessment of the patient or medical file by qualified health care professionals. For example, it may be acceptable to prescribe opioids to workers who are gainfully employed and not receiving time-loss. Similarly, the guidelines cannot substitute for detailed prescribing information found in many medical and pharmacologic references.

_____
Reference: Date Introduced: 1992

These guidelines will be applied in the workers' compensation setting only. The guidelines will apply only to workers whose injuries occurred after the guidelines are adopted by WSMA and sufficient notice has been given to providers. ***The Department of Labor and Industries may impose sanctions if the guidelines are not followed.***

The guidelines are intended for use by physicians who begin treatment within 6 months of the worker's injury. Patients who have been on controlled substances for prolonged periods and come under the care of a new physician present special problems. These and other problems will be dealt with in a separate publication.

Finally, while the guidelines may not conflict with state or federal laws, by necessity they cannot cover in detail all of the many rules, regulations, and policies published by the various agencies enacting and enforcing these laws.

Table 1

Documentation Recommendations When Controlled Substances Are Prescribed

a. A thorough medical history and physical examination and medical decision-making plan should be documented, with particular attention focused on determining the cause(s) of the patient's pain.

b. A written treatment plan should be documented and should include the following information:
   * a finite treatment plan that does not exceed six weeks.
   * clearly stated, measurable objectives.
   * a list of all current medications (with doses) including medications prescribed by other physicians (whenever possible).
   * description of reported pain relief from each medication.
   * justification of the continued use of controlled substances.
   * documentation of attempts at weaning.
   * explanation of why weaning attempts have failed (including detailed history to elicit information on alcohol and drug use).
   * how the patient's response to medication will be assessed.
   * further planned diagnostic evaluation.
   * alternative treatments under consideration.

c. The risks and benefits of prescribed medications should be explained to the patient and the explanation should be documented, along with expected outcomes, duration of treatment, and prescribing limitations.

d. The treatment plan should be revised as new information develops which alters the plan.

Table 2

Relative Contraindications For The Use Of Controlled Substances

1.	*History* of alcohol or other substance abuse, or a history or chronic, high dose of benzodiazepine use.
2.	*Active* alcohol or other substance abuse.
3.	*Borderline* personality disorders.
4.	*Mood disorders* (e.g., depression) or psychotic disorders.
5.	*Other* disorders that are primarily depressive in nature.
6.	*Off work* for more than 6 months.
*	Note: When special circumstances seem to warrant the use of these drugs in the types of patients noted above, referral for review is indicated.

General Information

A. Please refer to the "Introduction" for more information on the purpose, development, and application of these guidelines

PHYSICIANS MAY BE HELD ACCOUNTABLE IF THEIR PRESCRIBING PATTERNS FALL OUTSIDE THESE GUIDELINES.

B. Documentation recommendations (as presented in Table 1) should be followed at all times, especially whenever the physician departs from the guidelines listed below.

TREATMENT OF ACUTE PAIN FROM TRAUMATIC INJURIES OR SURGERY (POST-DISCHARGE):

A. Schedule II drugs should be prescribed for no longer than 2 weeks.

B. Schedule III and Schedule IV drugs should be prescribed for no longer than 6 weeks. (See Table 3 for examples of controlled substances.)

TREATMENT OF CHRONIC NON-MALIGNANT PAIN*:

A. **EXTREME CAUTION** should be used in prescribing controlled substances for workers with one or more "Relative Contraindications" (see Table 2). (NOTE: When special circumstances seem to warrant the use of these drugs in the types of patients listed in Table 2, referral for review is indicated.)

B. For patients on a **combination** of opioids and scheduled sedatives:

TREATMENT WITH COMBINATIONS SHOULD USUALLY NOT EXTEND BEYOND 6 WEEKS.

C. For patients on opioids **OR** scheduled sedatives (but not combinations of the two):

TREATMENT SHOULD USUALLY NOT EXTEND BEYOND 3 MONTHS.

D. Consultation or referral to a chronic pain specialist should be considered when any of the following conditions exist:

1. underlying tissue pathology is minimal or absent, **AND** correlation between the structural derangement caused by the original injury and the severity of impairment is not clear;

2. suffering and pain behaviors are present, and the patient continues to request medication;

3. standard treatment measures have not been successful or are not indicated.

* Defined as pain persisting beyond the expected healing time for an injury, for which traditional medical approaches have been unsuccessful.

Table 3

Examples Of Controlled Substances*

SCHEDULE II	SCHEDULE III	SCHEDULE IV
OPIOIDS: codeine fentanyl (Sublimaze, Innovar) hydromorphone (Dilaudid) levorphanol (Levo-Dromoran) meperidine (Demerol) meperidine w/ Promethazine (Mepergan) methadone (Dolophine) morphine (MS Contin, MSIR, OMS, RMS, Roxanol) oxycodone oxycodone w/ acetaminophen/aspirin (Percocet, Percodan, Roxicet, Roxiprin, Tylox)	OPIOIDS: acetaminophen with codeine (Codalan, Phenaphen 2, 3, 4, Tylenol 2, 3, 4) aspirin with codeine (Empirin 2, 3, 4) hydrocodone hydrocodone w/ acetaminophen/aspirin (Anexsia, Azdone, Bancap, Co-gesic, Damason-P, Dolacet, Duocet, Endal-HD, Hyco-Pap, Hydrocet, Hyphen, Lorcet Plus, Lorcet HD, Lortab, Vicodin, Zydone) nalorphine paregoric	OPIOIDS: propoxyphene (Darvon) propoxyphene w/ acetaminophen/aspirin (Darvocet, Dolene, Wygesic) pentazocine (Talwin)
SEDATIVES: amobarbital (Amytal)** secobarbital (Seconal)** pentobarbital (Nembutal)**	SEDATIVES: any compound containing an unscheduled drug and: amobarbital ** secobarbital** pentobarbital** glutethimide (Doriden) Non-narcotic Analgesic Combinations butalbital with acetaminophen/aspirin (fiorinal)	SEDATIVES: chloral hydrate clorazepate (Tranxene) chlordiazepoxide (Librium) clonazepam (Klonopin) diazepam (Valium) ethchlorvynol (Placidyl) flurazepam (Dalmane) meprobamate (Equanil, Miltown) oxazepam (Serax) paraldehyde (Paral) phenobarbital ** prazepam (Centrax) triazolam (Halcion)

* This table is not intended as an exhaustive listing of controlled substances. A few trade names have been given as examples. This listing should in no way be construed as an endorsement of any medication.

** Barbiturates are not paid for by the Department at any time (except phenobarbital, which is allowed only for seizure disorders).

TO OUR PATIENTS

WHAT YOU SHOULD KNOW ABOUT RULES YOUR DOCTOR MUST FOLLOW TO PRESCRIBE DRUGS THAT MAY BE ADDICTIVE.

The Washington State Medical Association (WSMA) and the Department of Labor and Industries (L&I) believe that it may do you more harm than good to take addicting drugs for a long time.

Guidelines approved by the Washington State Medical Association must be followed by your.

SO PLEASE HELP YOUR PHYSICIAN TO HELP YOU -- FOLLOW YOUR DOCTOR'S INSTRUCTIONS CAREFULLY.

THANK YOU!

A message from the Washington State Medical Association.

To the doctor: Please feel free to photocopy this sheet and distribute to your patient, preferably along with your first prescription for controlled substance.

Selected References

The following are a few of the published materials used to prepare these guidelines.

AHFS Drug Information '91, American Hospital Formulary Service, by the American Society of Hospital Pharmacists, Inc., Bethesda, MD, 1991.

"Chronic Opioid Therapy in Nonmalignant Pain," RK Portenoy, Journal of Pain and Symptom Management, Vol. 5, No. 1 (Suppl.) February 1990, pp. S46-S62.

Guidelines for Prescribing Controlled Substances for Chronic Conditions, California Medical Association, San Francisco, CA, April 12, 1985.

"Medications in Low Back Pain," JP Robinson and PB Brown, Physical Medicine and Rehabilitation Clinics of North America, Vol. 2, No. 1, February 1991, pp. 97-125.

"Prescribing Practices for Pain in Drug Dependence: A Lesson in Ignorance," LM Halpern and JP Robinson, Controversies in Alcoholism and Substance Abuse, The Haworth Press, Inc., 1986.

"Unlocking the Secrets of Pain — The Treatment — A New Era," JD Loeser, Medical and Health Annual Encyclopedia Britannica, 1988 pp 120-31.

Collaborative Guidelines On The Diagnosis Of Porphyria And Related Conditions

Prepared By

The Washington State Department of Labor and Industries
And
The Washington State Medical Association's
Committee On Industrial Insurance And Rehabilitation

October 18, 1995

Purpose and Development of these Guidelines

The purpose of these guidelines is to provide information for treating physicians and independent medical examiners to use in evaluating patients with possible exposure-related porphyria, and to provide a foundation for developing Department medical policy.

The focus of these guidelines is on the phase of the medical evaluation where a decision must be made whether to proceed with an extensive work-up to reach a definitive diagnosis, or to conclude that results of a preliminary evaluation make a diagnosis of porphyria unlikely (see Section III). It is beyond the scope of these guidelines to provide detailed algorithms for reaching a conclusive diagnosis.

These guidelines were developed with the input and approval of numerous nationally and internationally recognized experts on porphyria. Input was also incorporated from many other individuals, including physicians representing a wide variety of specialties and non-physicians with an interest in this topic.

The scientific basis for these guidelines, along with additional information about their development, can be found in a review document on porphyria prepared by the Office of the Medical Director of the Washington State Department of Labor and Industries. These guidelines may be revised as new scientific information becomes available.

Reference: Date Introduced: October 1995

General Information

Porphyrias are metabolic disorders in which the clinical manifestations are attributable to decreased activity of a specific enzyme(s) in the heme synthesis pathway, associated with characteristic patterns of overproduction of specific heme precursors and resultant accumulation in certain tissues. Each enzyme deficiency results in a predictable accumulation of the preceding heme precursor(s), and overall production of heme is generally preserved. Porphyrias, when clinically active, and in some cases even when latent or in clinical remission, are characterized by high levels of heme precursors in blood, urine, and/or stool. Most types of porphyria are inherited conditions; however, one type of porphyria, porphyria cutanea tarda, is known to occur in acquired or inherited manner.

Many of the tests used to diagnose the porphyrias are nonspecific and are abnormal in many circumstances other than the porphyrias. Porphyrinuria, i.e., increased urine porphyrins, can be caused by porphyrias, by a number of other medical conditions, and by a variety of exogenous factors such as alcohol and certain drugs and chemicals that disturb heme synthesis or stress heme-dependent metabolism. The term "secondary porphyrinuria" is commonly used in reference to the porphyrinuria occurring with conditions and factors lacking a primary enzyme defect in heme synthesis. It usually involves mild or moderate coproporphyrinuria, with no or little excess uroporphyrin in urine, and is also often called "coproporphyrinuria" or "secondary coproporphyrinuria."

In individuals who are genetically predisposed to developing an acute or cutaneous porphyria, manifestations of porphyria can be *triggered* by a variety of exogenous factors including alcohol, certain therapeutic drugs and chemicals, infections, dietary factors and sun exposure, as well as by certain medical conditions and endogenous factors such as menstruation and administered steroid hormones. Exogenous factors can also *cause* changes in the heme synthesis pathway, even in the absence of genetic predisposition; in some cases, these acquired changes have been reported to cause porphyria cutanea tarda.

Lead absorption, both acute and chronic, is well documented to affect heme synthesis. Lead causes accumulation of protoporphyrin in erythrocytes and large increases of ALA and coproporphyrin in urine. Lead inhibits ALA dehydratase, and also appears to interfere with the function of two other heme synthesis enzymes. Lead intoxication is generally classified as a secondary porphyrinuria rather than as an acquired porphyria, although it does have clinical and biochemical similarities with acute porphyrias.

A number of chemicals, primarily halogenated hydrocarbons and metals, are known to be "porphyrogenic" (i.e., capable of inducing changes in heme synthesis, with subsequent overproduction and excessive excretion of heme precursors) in experimental animals, generally with doses much greater than the range of human experience. In humans, with the noteworthy exceptions of porphyria caused by hexachlorobenzene and the "porphyrinuria" caused by lead, reports of porphyria or porphyrinuria attributable to chemical exposures have been infrequent. It must be acknowledged, however, that there

has been only limited systematic study of the subject in humans. The reported findings have generally been linked to chronic industrial exposures, industrial accidents, or environmental exposures that were much higher than normally encountered.

Diagnosis

The most important first step toward diagnosing or ruling out porphyria in a symptomatic patient is for the physician to maintain a high index of suspicion for a possible diagnosis of porphyria, whether symptoms are "classic" for a porphyria or are vague or unexplained. The conclusive diagnosis of a porphyria should be based on a systematic approach incorporating medical history, physical examination, and biochemical data, including genetic evaluation if necessary. Certain symptom patterns, physical findings, and elements of the exposure history may raise the degree of suspicion for porphyria; however, the lack of supporting information from these sources cannot exclude a diagnosis of porphyria. Therefore, the systematic approach to evaluating a symptomatic patient with suspected porphyria should begin with laboratory evaluation.

In a person with symptoms from a porphyria, the level of the most excessively excreted heme precursor is typically at least several-fold greater than the upper limit of values found in normal individuals.

A. Minimum ("Threshold") Criteria

Physicians must sometimes decide whether an extensive work-up for porphyria is indicated. In order to assist clinicians in this decision, the following threshold criteria are recommended:

In a patient who is currently or recently symptomatic and who is suspected to have a porphyria, it is not probable that the patient's symptoms are attributable to a porphyria of any type unless a measurement on at least one of the following tests is greater than twice the upper limit of normal:

- **urine porphobilinogen (PBG)**
- **urine uroporphyrin**
- **urine coproporphyrin**
- **fecal coproporphyrin**
- **blood total porphyrins**

B. Caveats

1. **Reference range:** Because a reference range may be unique to the assay method and the individual laboratory performing the test, test results should be interpreted relative to the laboratory-specific reference range and/or, if sufficient general clinical experience exists, against accepted absolute reference standards.

2. **Blood Lead Level:** A blood lead level should be checked to determine the possibility of lead intoxication if lead exposure is suspected, if excretion of coproporphyrin or ALA is increased, or if blood porphyrins (e.g., blood zinc protoporphyrin [ZPP]) are increased.

3. **Repeat testing and factors affecting test results:** Laboratory test results, in general, can be compromised by a variety of factors including specimen integrity, analytical quality, limitations of analytical methods, and the applicability and specificity of reference ranges or "control" data. Issues of specimen integrity may be particularly relevant when specimens are collected and processed at one site, and then transported to a geographically distant reference laboratory.

   Because of these risks, an abnormal test result generally should be confirmed by analysis of a second specimen before the test result is used to finalize a diagnostic conclusion. The need to repeat a test, of course, must be tempered by the degree of support for a diagnosis from other clinical and laboratory data, and by the feasibility of repeating the test (i.e., the appropriate clinical circumstances should still be present).

4. **Enzyme measurements:** If a person is currently or recently symptomatic and is found to have reduced activity of a specific heme synthesis enzyme, but laboratory testing does not also reveal overproduction and excessive excretion of heme precursors in a pattern and levels consistent with the porphyria specific to that enzyme, then the reduction in measured enzyme activity has no probable causative relationship to the person's symptoms.

5. **Additional testing:** Satisfaction of these "twice the upper limit of normal" criteria *does not necessarily establish* a diagnosis of porphyria. Depending on the degree and pattern of abnormalities on these tests, additional testing may be necessary to establish or exclude a diagnosis of porphyria. It is possible that an individual could have an abnormal heme precursor measurement with this degree of abnormality (i.e., twice upper normal) as a consequence of something other than porphyria (or lead intoxication). Other medical conditions can cause "secondary" porphyrinuria of this magnitude. Blood porphyrins can also be increased by this magnitude in conditions other than porphyria: for example, iron deficiency commonly produces an increase in blood zinc protoporphyrin (ZPP).

6. **Timing of specimen collection:** Conversely, failure to satisfy these "twice the upper limit of normal" criteria *does not necessarily exclude* a diagnosis of porphyria. Heme precursor measurements in the range of one to two times the upper normal value should not be interpreted as "normal," but rather as *indeterminate or non-diagnostic.* When a patient with suspected porphyria is not currently or recently symptomatic, the levels of heme precursor excretion are generally lower and can even normalize with time. If a patient's last symptoms

occurred remotely in time relative to specimen collection, it may be necessary to repeat the tests during or as soon as possible after future symptoms.

7. **"Secondary porphyrinuria":** Porphyrinuria sometimes secondarily reflects the presence of a medical condition or exogenous factor that disturbs heme synthesis or stresses heme-dependent metabolism but produces symptoms through a separate mechanism. With the noteworthy exception of lead poisoning, the porphyrin excess in "secondary porphyrinuria" has no recognized, clinically detectable consequences of its own; symptoms associated with secondary porphyrinuria (other than lead poisoning) are attributed by most experts to the condition or agent causing the porphyrinuria, or to an unrelated cause, and not to a disturbance in heme synthesis. Although the porphyrinuria itself may be benign, the associated medical condition may be far from benign.

   Medical conditions that appear to have only secondary effects on the heme synthesis pathway are appropriately evaluated with attention focused on the primary condition. Similarly, when chemical exposures are suspected as the cause of a patient's symptoms or medical condition, the exposure relationship can be characterized more specifically by assessment of the exposure situation or by quantification of the suspected chemical (or its metabolite) in blood or urine, than by measurement of heme precursors.

Complex Regional Pain Syndrome (CRPS)

Formerly known as Reflex Sympathetic Dystrophy

1. INTRODUCTION

This bulletin outlines the Department of Labor and Industries' guidelines for diagnosing and treating Complex Regional Pain Syndrome (CRPS) – formerly known as Reflex Sympathetic Dystrophy (RSD). This guideline was developed through collaboration between the Washington State Medical Association (WSMA) Industrial Insurance/Rehabilitation Committee and the Office of the Medical Director of the Department of Labor and Industries. The protocol for CRPS physical therapy/occupational therapy (see Table 2) was developed in collaboration with the Washington State Physical Therapy and Occupational Therapy Associations.

2. WHAT IS COMPLEX REGIONAL PAIN SYNDROME?

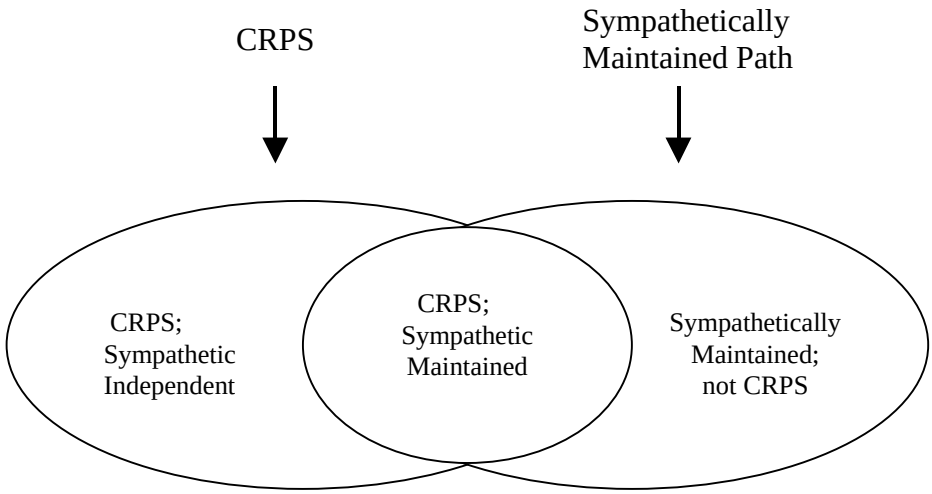
Complex Regional Pain Syndromes are painful conditions that usually affect the distal part of an upper or lower extremity and are associated with characteristic clinical phenomena as described in Table 1. There are two subtypes – CRPS Type I and CRPS Type II.

The term "Complex Regional Pain Syndrome" was introduced to replace the terms "reflex sympathetic dystrophy." CRPS Type I used to be called reflex sympathetic dystrophy. CRPS Type II used to be called causalgia. The terminology was changed because the pathophysiology of CRPS is not known with certainty. It was determined that a descriptive term such as CRPS was preferable to "reflex sympathetic dystrophy" which carries with it the assumption that the sympathetic nervous system is important in the pathophysiology of the painful condition.

The terms CRPS Type I and CRPS Type II are meant as descriptors of certain chronic pain syndromes. They do not embody any assumptions about pathophysiology. For the most part the clinical phenomena characteristics of CRPS Type I are the same as seen in CRPS Type II. The central difference between Type I and Type II is that, by definition, Type II occurs following a known peripheral nerve injury, whereas Type I occurs in the absence of any known nerve injury.

Reference: Provider Bulletin 97-05; Date Introduced: Jun. 97'

Pain that can be abolished or greatly reduced by sympathetic blockade (for example, a stellate ganglion block) is called sympathetically maintained pain. Pain that is not affected by sympathetic blockade is called sympathetically independent pain. The pain in some CRPS patients is sympathetically maintained; in others, the pain is sympathetically independent. The relation between CRPS and sympathetically maintained pain can be seen in the following Venn diagram:



**********PHYSICIANS PLEASE NOTE**********

If you believe the CRPS conditions is related to an *accepted occupational injury*, please provide written documentation of the relationship (on a more probable than not basis) to the original condition. Treatment for CRPS will only be authorized if the relationship to an accepted injury is established.

3. DIAGNOSTIC CODES

After treatment authorization has been obtained from the claim manager, physicians should use billing codes that are designated for reflex sympathetic dystrophy in the International Classification of Diseases (ICD-9CM) to bill. The relevant code numbers are described below:

ICD 9-CM Code	English Description
337.20	Reflex sympathetic dystrophy, unspecified
337.21	Reflex sympathetic dystrophy of the upper limb
337.22	Reflex sympathetic dystrophy of the lower limb
337.29	Reflex sympathetic dystrophy of other specified site

4. KEY ISSUES IN MAKING A DIAGNOSIS

A. CRPS is a Syndrome – See whether your patient's symptoms and signs match those described in Table 1.

B. CRPS is Uncommon - Most patients with widespread pain in an extremity do **NOT** have CRPS. **Avoid the mistake of diagnosing CRPS primarily because a patient has widespread extremity pain that does not fit an obvious anatomic pattern.** In many instances, there is no diagnostic label that adequately describes the patient's clinical findings. It is often more appropriate to describe a patient as having "regional pain of undetermined origin" than to diagnose CRPS.

C. Is CRPS a Disease? – Many clinicians believe that CRPS can best be construed as a "reaction pattern" to injury or to excessive activity restrictions (including immobilization) following injury. From this perspective, CRPS may be a complication of an injury or be iatrogenically induced but it is not an independent disease process.

D. Type I CRPS vs. Type II CRPS – In a patient with clinical findings of CRPS, the distinction between Type I and Type II CRPS depends on the physician's assessment of the nature of the injury underlying the CRPS. In many situations, the distinction is obvious – if CRPS onsets following an ankle sprain or a fracture of the hand, it is Type I CRPS. If CRPS onsets following a gunshot wound that severely injures the median nerve, it is Type II CRPS. In ambiguous situations (for example CRPS in the context of a possible lumbar radiculopathy), the physician should be conservative in diagnosing Type II CRPS. This diagnosis should be made only when there is a known nerve injury with definable loss of sensory and/or motor function.

5. TYPICAL CLINICAL FINDINGS

A diagnostic algorithm that details the following clinical findings is located in Table I at the end of this guideline.

A. History

1. Symptoms develop following injury (usually symptoms begin within 2 months post injury).
2. Onset is in a single extremity
3. Burning pain
4. Hyperalgesia or allodynia (allodynia means pain elicited by stimuli that normally are not painful, i.e., a patient reports severe pain in response to gentle stroking of the skin.)
5. Swelling
6. Asymmetry or instability of temperature or color

7. Asymmetry or instability of sweating
8. Trophic changes of skin, nails, hair

B. Findings by Examination

1. Hyperalgesia or allodynia
2. Edema (if unilateral, and other causes excluded)
3. Vasomotor changes such as asymmetry or instability of temperature/color
4. Sudomotor changes such as excess perspiration in affected extremity
5. Trophic changes such as shiny skin, hair loss, abnormal nail growth
6. Findings suggestive of impaired motor function such as:

(a) tremor
(b) abnormal limb positioning
(c) diffuse weakness that cannot be explained by neuralgic loss or by dysfunction of joints, ligaments, tendons or muscles.

C. Diagnostic Test Results

A three-phase bone scan with characteristic pattern of abnormality. (NOTE – An abnormal bone scan is **not** required for the diagnosis of CRPS.)

D. Lack of Reasonable Alternative

No other anatomic, physiologic or psychological condition that would reasonably account for the patient's pain and dysfunction.

6. SYMPATHETIC BLOCKADE IN THE DIAGNOSIS OF CRPS

A. CRPS is considered a clinical syndrome, based on the criteria previously described in typical clinical findings and detailed in Table 1.

B. A patient's response to a diagnostic sympathetic block provides information about whether his/her pain is sympathetically maintained, but neither establishes nor refutes a diagnosis of CRPS. Therefore, a sympathetic block is not considered to be a definitive diagnostic test for CRPS.

C. In the patient with CRPS the purpose of a sympathetic block is to guide treatment. If a CRPS patient responds positively to a sympathetic block (indicating that his/her pain is sympathetically maintained) repeat blocks might be useful in the overall treatment plan.

D. If a patient does NOT meet the criteria for diagnosing CRPS as given in Table I, but the attending physician feels that the patient has sympathetically maintained pain, you may request authorization for a diagnostic sympathetic block. Requests to the state fund for a diagnostic sympathetic block should be sent to the L&I Office of the Medical Director for review.

7. AN OVERVIEW OF TREATMENT

Experts in CRPS believe the probability of a patient developing this condition can be reduced by early mobilization/activation following injury or surgery. Conversely, unnecessarily prolonged immobilization following injury or surgery may set the stage of iatrogenic CRPS. Therapy for CRPS should be directed toward the goals of physical restoration and pain control. Details regarding treatment are presented in Tables 1 and 2 located at the end of this Guideline.

A. Physical Restoration

Experts agree that CRPS patients usually become trapped in a vicious cycle in which guarding and activity restrictions perpetuate the pain of CRPS. Therapy for CRPS should be directed toward breaking the pain cycle by having patients participate in a progressive activation program for the affected limb.

1. Because patients usually resist using the affected extremity, the physical restoration program generally requires supervision by a physical therapist or occupational therapist.
2. Involvement of a physical or occupational therapist is important so that repeated measurements of a patient's functional capacity can be made.
3. The frequency with which a patient receives physical or occupational therapy must be individualized by the attending physician.
4. Physical or occupational therapy occasionally continues beyond the time period during which pain control interventions such as sympathetic blocks are administered. Such prolonged therapy will be authorized as long as there is evidence of ongoing improvement of function of the limb.
5. Patients need to understand they must use their symptomatic limb in the course of their usual daily activities as well as during physical or occupational therapy sessions. Patients must commit themselves to physical restoration on a 24-hour per day basis.

B. Pain Control

1. Interventions to reduce pain are typically needed so that patients can get enough relief to participate in an activation program.
2. It is crucial that pain control interventions be linked closely with physical/occupational therapy. Physical or occupational therapy sessions should be scheduled as soon as possible after a sympathetic block. The interval between block and therapy should always be less than 24-hours. In general, physical/occupational therapy should be directed toward activation and desensitization in the affected limb. Details are given in Table 2.
3. Clinicians use a variety of medications to control pain in patients with CRPS. These include alpha adrenergic blockers, corticosteroids, antidepressants, anti-seizure medications, mexiletine and opiates. The Department of Labor and Industries has no formal guideline regarding a specific medication regimen for CRPS.

C. Sympathetic Blocks

1. In a patient who meets criteria for CRPS, up to 3 sympathetic blocks will be authorized to allow the attending physician to determine whether the patient has sympathetically mediated pain.

2. Additional blocks will be authorized ONLY if there is evidence from the first three that the patient has sympathetically mediated pain.

3. The physician who performs each sympathetic block should document:
   (a) Measurable evidence that a sympathetic blockade in the target limb was achieved – e.g., hand/foot temperature before and after the block, observed color changes and/or venodilation.
   (b) The extent and duration of the patient's pain relief, based on a pain diary.

4. A patient should be seen by a physical or occupational therapist during the time interval when a sympathetic block would be expected to have an effect – that is, within a few hours of the block. The therapist should document the functional status of the patient's symptomatic limb during the therapy session.

5. The attending physician or the physician performing sympathetic blocks should correlate the information previously described n #3 and #4 to determine whether a block has produced the intended effects on pain, function and observable manifestations of CRPS.

D. Psychological Treatment

The clinical course of many patients with chronic pain, such as those with CRPS, may be complicated by pre-existing or concurrent psychological or psychosocial issues. A one time psychological/psychiatric consultation may be requested to assist in the evaluation of such patients.

For those patients you feel require treatment for psychological/psychiatric disorders, authorization for such treatment will be considered only under the following conditions:

The psychological/psychiatric consultation has led to a psychiatric diagnosis (that is, a DSM4 diagnosis),

AND 1) **EITHER** the diagnosed psychiatric condition must be considered causally related to the industrial injury,

2) **OR** the diagnosed condition must be retarding recovery from the industrial injury.

E. Treatment Phases

Treatment is divided into six-week phases. A maximum of three phases may be authorized. The second phase will be authorized only if the first phase has led to demonstrable functional improvement. The third phase may be authorized only if the first and second phases have led to demonstrable functional improvement.

1. In the first six-week phase, up to 5 sympathetic blocks will be authorized (along with other accepted conservative measures such as medication management).

2. During the second six-week phase, a total of 3 sympathetic blocks will be authorized.
3. Up to 3 more sympathetic blocks may be authorized for patients who go on to the third phase of treatment.

F. Hospitalization

Hospitalization is rarely appropriate in the treatment of CRPS. The only exception to this is that a CRPS patient might have an orthopedic condition that is amenable to surgery. Because CRPS patients are at high risk for flares after surgery, it is reasonable for such a patient to be admitted to a hospital prior to surgery so that aggressive pain control measures may be undertaken preoperatively.

G. Sympathectomy

Sympathectomies are not indicated for CRPS and are NOT COVERED.

8. REFERENCES

1. Janig W & Stanton-Hicks M (ed) Reflex Sympathetic Dystrophy: A Reappraisal. Seattle: IASP Press, 1996.
2. Merskey H & Bogdud N (ed) Classification of Chronic Pain (2nd ed). Seattle: IASP Press 1994.

Table 1
Labor And Industries
Criteria Number 13
Chronic Regional Pain Syndrome (CRPS)
Conservative Treatment Guideline

EXAMINATION FINDINGS & DIAGNOSTIC TEST RESULTS

At least **four** of the following **must be present** in order for a diagnosis of CRPS to be made.

EXAMINATION FINDINGS:

1. Temperature/color change
2. Edema
3. Trophic skin, hair, nail growth abnormalities
4. Impaired motor function
5. Hyperpathia/allodynia
6. Sudomotor changes

DIAGNOSTIC TEST RESULTS

7. Three-phase bone scan that is abnormal in pattern characteristics for CRPS. This test is not needed if 4 or more of the above examination findings are present.

SURGICAL INTERVENTION (SYMPATHETECTOMY) FOR TREATMENT OF THIS CONDITION IS NOT COVERED

CONSERVATIVE CARE

Early aggressive care is encouraged. Emphasis should be on improved functioning of the symptomatic limb.

FIRST SIX WEEKS OF CARE:

- Sympathetic blocks, maximum of **five**. Each block should be followed immediately by physical/occupational therapy.
- Physical/occupational therapy should be focused on increasing functional level (see Table 2).
- Other treatment, e.g., medication at MD's discretion as long as it promotes improved function.

AFTER THE 1ST SIX WEEKS OF CARE:

- Strongly consider psychiatric or psychological consultation if disability has extended beyond 3 months.
- Continued physical/ occupational therapy based on documented progress towards goals established during first 6 weeks (referenced above).
- Sympathetic blocks only if response to previous blocks has been positive, maximum of 3** every six weeks for a maximum of 12 weeks.

****A maximum of 11 blocks can be delivered over the total 18 week period.**

Table 2

Labor And Industries
Criteria Number 13
Chronic Regional Pain Syndrome (CRPS)
Conservative Treatment Guideline

PROTOCOL FOR PHYSICAL THERAPY/OCCUPATIONAL THERAPY FOR CRPS

1. Evaluation should:
- **A.** Include a date of onset of original injury (helpful in determining if early or late stage) and a date of onset of the CRPS symptoms.
- **B.** Establish a baseline for strength and motion.
- **C.** Establish a baseline for weight bearing for lower extremity.
- **D.** If lower extremity, evaluate distance able to walk and need for assistive device.
- **E.** If upper extremity, establish a baseline for grip strength, pinch strength and shoulder range of motion.
- **F.** If possible, objectify swelling (e.g., do volume displacements).
- **G.** Define functional limitations.

2. Set specific functional goals for treatment related to affected extremity.

3. All treatment programs should include a core of:
- **A.** A progressive active exercise program, including a monitored home exercise program.
- **B.** Progressive weight bearing for the lower extremity (if involved).
- **C.** Progressive improvement of grip strength, pinch strength and shoulder range of motion of the upper extremity (if involved).
- **D.** A desensitization program.

4. For specific cases, additional treatment options may be indicated to enhance effectiveness of the above core elements. Documentation should reflect reasons for these additional treatment options.

5. Documentation should include:
- **A.** At least every two weeks, assessment of progress towards goals.
- **B.** Response to treatment used in addition to core elements (listed above in section 3).
- **C.** Evidence of motivation and participation in home exercise program, i.e., diary or quota system.

Fibromyalgia

Purpose

Fibromyalgia is a complex pain disorder that raises many questions for providers, particularly as to whether this condition is related to the industrial insurance system. The purpose of this bulletin is to answer a few of those questions:

- Is fibromyalgia accepted as an industrial injury or occupational disease?
- If a provider asserts a worker's fibromyalgia is related to the industrial injury or occupational exposure, what type of documentation should be submitted to support this contention?
- Will the department or self-insurer pay for short-term treatment of fibromyalgia?

Is fibromyalgia accepted as an industrial injury or occupational disease?

The Office of the Medical Director at the Department of Labor & Industries, in collaboration with the Washington State Medical Association's Industrial Insurance Guideline Subcommittee, studied fibromyalgia and the medical literature that addresses the causes of fibromyalgia. After careful consideration, it was determined that there is not sufficient medical data at this time to establish a causal relationship between an industrial injury or occupational exposure and the subsequent development of fibromyalgia.

Based on this lack of scientific evidence, the department does not generally recognize fibromyalgia as an industrial injury, an occupational disease, or an aggravation to a pre-existing condition.

The worker's health care provider may submit additional information, as described below, that the provider believes rebuts, or challenges, this general policy for an individual worker.

Reference: Provider Bulletin 98 – 11; Date Introduced: November 98'

If a provider asserts a worker's fibromyalgia is related to the industrial injury or occupational exposure, what type of documentation should be submitted to support this contention?

A provider who feels that a worker's fibromyalgia is causally related to an industrial injury or occupational disease is encouraged to submit additional information to support that diagnosis. The kinds of information useful in this regard include:

1. **Case-specific information linking the injury to the occurrence of fibromyalgia,**
   Case-specific information might include, but is not limited to:
- Evidence of a temporal relationship to the worker's industrial injury or occupational exposure (e.g. the injury precedes all symptoms of fibromyalgia or symptoms of potentially crossover disorders such as chronic fatigue syndrome),
- Documentation that the worker's diagnosis of fibromyalgia meets the American College of Rheumatology's 1990 Criteria for the Classification of Fibromyalgia (see attachment),
- A biological and clinically justifiable rationale for the relationship between the industrial injury and the occurrence of fibromyalgia. The biological rationale should include a discussion based on accepted principles of biological sciences (anatomy, physiology, biochemistry, etc.) as to how the industrial injury caused the condition.

2. **Scientific studies that address the relationship between individual injuries and the occurrence of fibromyalgia.**
   The provider is encouraged to submit published scientific studies supporting the contention of causality. In 1996, and again in 1997 and 1998, the department reviewed the existing scientific literature on this subject and found insufficient medical data to establish a causal relationship between a traumatic injury or occupational exposure and the development of fibromyalgia. Therefore, it is particularly important that the provider point out any new studies or new analyses of old studies that he or she feels supports a different conclusion regarding causality.

Effective January 1, 1999, State Fund claim managers will automatically request this information from the attending physician whenever fibromyalgia is contended on a claim. Information submitted by the provider to support the causal relationship will be reviewed by department medical staff before a claim adjudication decision is made.

Will the department or self-insurer pay for short-term treatment of fibromyalgia?

Temporary treatment as an aid to recovery
In general, fibromyalgia is not an accepted condition and treatment is not allowed. However, if fibromyalgia is directly retarding recovery of the accepted industrial injury or occupational disease, the department or self-insurer may authorize temporary treatment per WAC 296-20-055. Temporary treatment can be authorized when all of the following conditions are met:

- The accepted industrial injury is not stable,
- Fibromyalgia is directly retarding recovery of the accepted industrial injury or occupational disease, and
- The required documentation is submitted (see authorization and documentation requirements below).

Treatment as an aid to recovery will be authorized for no longer than 90 calendar days. If the worker has reached maximum recovery from the accepted industrial injury or occupational disease prior to the 90-day period, the fibromyalgia treatment will be terminated at that time.

What are the authorization requirements?
The provider must obtain prior authorization to treat fibromyalgia as an aid to recovery. The department or self-insurer will not pay for treatment for fibromyalgia as an unrelated condition unless specifically authorized.

To request prior authorization, the provider must submit the following in writing to the department or self-insurer:
- Adequate documentation that the worker's diagnosis of fibromyalgia meets the American College of Rheumatology's (ACR) 1990 Criteria for the Classification of Fibromyalgia (see attachment A),
- An explanation of how fibromyalgia, as an unrelated condition, is affecting the accepted industrial condition, and
- A treatment plan.

Note: The State Fund's Provider Toll Free staff will not be able to authorize these services.

What type of treatment may be allowed for the temporary treatment of fibromyalgia?
The department or self-insured employer is most likely to approve treatment plans that include conservative, non-invasive treatment that the scientific literature has shown to be effective in the short term. Such treatment includes, but may not be limited to:
- Physical therapy,
- Low dose tricyclic anti-depressants,
- Muscle relaxants on a time-limited basis, or
- Spinal manipulations.

The department or self-insured employer will **not** approve invasive therapies or treatments whose effectiveness has not been documented for even the short-term. The following types of treatment will not be approved for the treatment of fibromyalgia:

- Trigger point injections,
- Methotrexate,
- Opioids, or
- NSAIDS.

Note: Fibromyalgia may coexist with other conditions for which such therapies may be indicated.

What are the documentation requirements?
When treating an unrelated condition, the attending physician must submit a report every 30 days outlining the effect of the treatment on both the unrelated and the accepted industrial conditions.

Because fibromyalgia does not have a unique diagnosis code, we ask that providers use ICD.9 code 729.1 (myalgia) on bills submitted for treatment of fibromyalgia.

Where is more information available?

Temporary treatment of unrelated conditions when retarding recovery
WAC 296-20-055

Criteria for the classification of fibromyalgia

- Enclosed summary, attachment A.
- Frederick Wolfe, et.al., "The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia, Report of the Multicenter Criteria Committee," *Arthritis and Rheumatism,* Vol. 33, No. 2, (February 1990).

ATTACHMENT A

The American College of Rheumatology's 1990 Criteria for the Classification of Fibromyalgia*

For classification purposes, patients will be said to have fibromyalgia if both criteria are satisfied. Widespread pain must have been present for at least 3 months. The presence of a second clinical disorder does not exclude the diagnosis of fibromyalgia.

1. History of widespread pain.

Pain is considered widespread when all of the following are present: pain in the left side of the body, pain in the right side of the body, pain above the waist, and pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present. In this definition, shoulder and buttock pain is considered as pain for each involved side. "Low back" pain is considered lower segment pain.

2. Pain, on digital palpation, must be present in at least 11 of the following 18 tender point sites:

Occiput - bilateral, at the suboccipital muscle insertions
Low cervical - bilateral, at the anterior aspects of the intertransverse spaces at C5-C7
Trapezius - bilateral, at the midpoint of the upper border
Supraspinatus - bilateral, at origins, above the scapula spine near the medial border
Second rib - bilateral, at the second costochondral junctions, just lateral to the junctions on upper surfaces
Lateral epicondyle - bilateral, 2 cm distal to the epicondyles
Gluteal - bilateral, in upper outer quadrants of buttocks in anterior fold of muscle
Greater trochanter - bilateral, posterior to the trochanteric prominence
Knee - bilateral, at the medial fat pad proximal to the joint line

Digital palpation should be performed with an approximate force of 4 kg. For a tender point to be considered "positive" the subject must state that the palpation was painful. "Tender" is not to be considered "painful".

* Frederick Wolfe, et.al., "The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia, Report of the Multicenter Criteria Committee", Arthritis and Rheumatism, Vol. 33, No. 2 (February 1990)